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

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

5 November 2026

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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 decisions made by a delegate of the Secretary of the Department of Health and Aged Care responsible for scheduling of medicines and chemicals (the Delegate)[1] under regulation 42ZCZN in relation to proposed amendments to the current Poisons Standard which were referred to an expert advisory committee[2] under subdivision 3D.2 of the Regulations in November 2025.
- the proposed date of effect of the proposed amendments (in circumstances where the interim decision proposes an amendment to the current Poisons Standard).

In accordance with regulation 42ZCZP, interested persons (including the applicant requesting the amendment) are invited to make submissions to the Secretary in relation to these interim decisions on or before **4 December 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 be 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 decisions on proposed amendments referred to the Advisory Committee on Medicines Scheduling (ACMS #48)

Interim decision in relation to isotretinoin

Proposal

The applicant proposed to amend the Appendix D, clause 2 entry for isotretinoin to extend prescribing to medical practitioners with advanced qualifications in general practice from the Royal Australian College of General Practitioners (RACGP) and the Australian College of Rural and Remote Medicine (ACRRM).

Isotretinoin is currently captured in Schedule 4 of the Poisons Standard and is subject to Appendix D, clause 2 restrictions, with mandatory pregnancy warnings under Appendices F and L. The current Appendix D entry for isotretinoin limits prescribing to specialist physicians and dermatologists.

Interim decision

Pursuant to regulation 42ZCZN of the Regulations, the Delegate has, in relation to the proposed amendment, made an interim decision to not amend the current Poisons Standard in relation to isotretinoin. The detailed reasons for the decision are provided within.

Materials considered

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

- the application to amend the current Poisons Standard with respect to isotretinoin (the Application)
- the 393 public submissions, with 281 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 48th 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 SPF, and
- the Handbook.

Summary of Committee advice to the Delegate

The Committee recommended that no change be made to the scheduling of isotretinoin as the current Poisons Standard entries remain appropriate.

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; 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:

– Isotretinoin is highly teratogenic (can cause birth defects).

– Accepted adverse effects include local irritation, skin dryness and flare-ups.

– Correlational but not necessarily causal concerns exist regarding mental health and sexual function.

Benefits:

– Isotretinoin is a very effective treatment for severe acne.

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

– The intended use is for the treatment of severe acne in accordance with established therapeutic guidelines.

– Off-label use for other conditions is recognised to occur.

c) the toxicity of a substance

– Although patient toxicity is generally limited and well characterised, foetal toxicity is high

– It is highly teratogenic, with 20–35% of pregnancies exposed resulting in irreversible birth defects including craniofacial, cardiovascular, and neurological malformations.

– It is associated with mood instability, suicidality, and liver injury.

– Treatment initiation can cause acute flare-ups requiring close monitoring, with potential mental health impacts.

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

– Standard dosing of oral isotretinoin is 0.5 to 1 mg/kg/day, divided into one or two doses.

e) the potential for abuse of a substance

– Nil.

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

– Psychological adverse outcomes (suicide, depression, sexual dysfunction, worsening scarring) warrant consideration given the increasing mental health burden in Australia, particularly among adolescents.

– Public feedback raised concerns that without specialist dermatology involvement there may be off-label use for less severe acne or cosmetic purposes.

– Internationally, most jurisdictions (UK, USA, Europe, Canada) have restricted prescribing.

– As a substance for treatment of acne, there is a risk of inappropriate access via the current single-product-based telehealth prescribing model. However, recent specialist dermatology telehealth services and high-definition imaging have also improved access to specialist care, supporting timely initiation and follow-up.

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

I have made an interim decision not to amend the current Poisons Standard in relation to isotretinoin.

I gave significant weight to the well-established safety concerns associated with isotretinoin, namely teratogenicity, and the specialist clinical knowledge and skills required for treatment initiation and ongoing management. The risk of teratogenicity in particular has formed the basis of the current longstanding requirement that treatment be initiated by a dermatologist. The material considered in making this decision did not demonstrate that the proposed change would maintain a level of safety equivalent to that provided under the existing scheduling. The material considered also did not substantiate the Application claim of an existing significant access barrier that the proposed change would address.

A total of 393 public submissions were received during the pre-meeting consultation: 383 opposed, 5 supported, and 5 partially supported the proposal. The overwhelming majority of submissions highlighted the risk of teratogenicity, the clinical complexity of safe and appropriate initiation and monitoring (including the need for robust pregnancy-prevention measures), the potential for misdiagnosis of mimicking conditions such as acne, and the potential for inappropriate use in patients with non-severe disease. Overall, submissions opposing the proposed change asserted that expanded prescribing risked weakening the existing appropriate safeguards.

The small number of public submissions that supported or partially supported the proposal contended that permitting appropriately trained general practitioners (GPs) to initiate isotretinoin may improve access, particularly in rural and remotes areas, and enhance continuity of care. Both the Application and supporting submissions suggested additional training requirements and prescribing protocols to support safe prescribing. However, robust evidence to demonstrate equivalent safety outcomes was not provided. Nor did the application and supporting submissions provide a plan for a training framework to ensure that existing safeguards would be maintained.

The Application contended that the current scheduling is a barrier to patient access, particularly in rural and remote areas. However, most submissions and the Committee advice suggest that this is not a significant barrier due to advancements in digital imaging technology and the availability of dermatologist-led telehealth services. These services appear to assist in addressing access concerns while maintaining the existing level of regulatory control.

Overall, the concerns raised in the majority of public submissions align with those identified by the Committee and support my conclusion that the current scheduling remains appropriate to balance access to treatment with patient safety.

In considering the risks and benefits of isotretinoin under sections 52E(1)(a), (b) and (c), I acknowledge that it is a highly effective therapy for severe acne and provides substantial therapeutic benefit to certain patients. However, these benefits must be weighed against the significant and well-established risks including teratogenicity, psychiatric adverse effects, liver injury, and severe acne flares requiring specialist management. Of particular concern is the well-documented teratogenicity of isotretinoin, with exposure during pregnancy associated with major congenital malformations and adverse pregnancy outcomes including miscarriage. Safe use requires comprehensive pregnancy prevention measures, structured patient counselling, regular monitoring, and careful dose titration.

While standard dosing regimens for isotretinoin are well established, when considering section 52E(1)(d), safe initiation and dose adjustment require individualised clinical assessment, consideration of comorbidities and risk factors, and ongoing laboratory monitoring. The Application did not adequately address how safeguards relating to diagnosis, pregnancy prevention, monitoring requirements, and dose titration would be implemented and overseen if initiation were expanded to GPs as proposed. Consequently, I am not satisfied that these safeguards could be maintained if initiation prescribing were broadened to include GPs. I also note updates to the Product Information for isotretinoin products in 2025 to strengthen warnings relating to psychiatric and sexual adverse effects[3] and emphasise the need for assessment before treatment, monitoring during treatment, and

[3] New safety warnings for isotretinoin (Roaccutane) | Therapeutic Goods Administration (TGA)

cessation of therapy where concerning symptoms emerge. These updates further reinforce isotretinoin's risk profile and the need for a high level of clinical oversight throughout treatment.

I note the Committee's view that the proposal largely concerns questions of prescriber qualifications and professional scope of practice rather than the benefits and risks of the substance itself. Current arrangements allow GPs to continue isotretinoin prescribing, thereby supporting access and continuity of care, while maintaining dermatologist oversight at the point of treatment initiation. The Poisons Standard establishes uniform controls on medicines and poisons in Australia and is supported by and intersects with state and territory poisons legislation, prescriber training and accreditation, and clinical practice guidance. Scheduling decisions must take into account many criteria including the purpose of use, safety in use, and the need for the substance. The Application did not include information on proposed frameworks for training, accreditation, monitoring, or risk management capable of providing assurance that the current safety standards would be maintained for isotretinoin if the proposed scheduling change was made.

I considered the available evidence from overseas jurisdictions, including New Zealand, where access arrangements for isotretinoin have been broadened. While some reports suggest improved access for Māori populations and patients from lower socioeconomic groups, the evidence regarding safety outcomes is limited. I note the Committee's observation that available data may indicate an increase in isotretinoin-exposed pregnancies as a result of broader prescribing. While the evidence is not conclusive, it does not provide assurance that broader initiation prescribing can be implemented without compromising safety. I note that international regulatory approaches generally continue to rely on specialist dermatologist involvement and/or strict pregnancy prevention programs, reflecting the significant risks associated with isotretinoin therapy. For these reasons, I am not satisfied that the potential benefits of broadening the current scheduling outweigh the potential risks to public health.

With respect to section 52E(1)(e), I acknowledge that isotretinoin has no recognised potential for abuse.

With respect to section 52E(1)(f), I share the Committee's concerns that expanding the scheduling of isotretinoin to allow GPs to initiate treatment may increase the risk of inappropriate prescribing for mild acne and other off-label uses, and also the risk of misuse through low-engagement telehealth and cosmetic services that may not consistently apply best practice clinical care. Single-product isotretinoin prescribing models targeting consumers online and via social media, particularly young people, present a real potential risk from the proposed expanded scheduling. These services are increasing in prevalence, and we have already seen their impact with other substances including cannabis and glucagon-like peptide-1 receptor agonists.

Having considered the Application, the Submissions, the Committee's advice, and the matters set out in section 52E of the Act, as well as international regulatory approaches and product labelling warnings, I am not satisfied that a case has been established for amending the current scheduling for isotretinoin. The substantial and well-established risks associated with isotretinoin, particularly its teratogenicity, the absence of evidence demonstrating that expanded initiation prescribing would maintain an equivalent standard of safety, and the continuing need for rigorous specialist oversight all support retention of the existing controls. On the available evidence, I consider the existing scheduling for oral isotretinoin remains appropriate to support the quality use of medicines and protect public health and safety in Australia.

My interim decision is that no amendment be made to the current Appendix D, Item 2 restrictions for isotretinoin.

Interim decision in relation to efepoetin alfa

Proposal

The Delegate initiated a proposal for the creation of new Prescription Only medicine (Schedule 4) and Appendix D, Clause 5 (Poisons for which possession without authority is illegal) entries for efepoetin alfa.

Efepoetin alfa is not clearly captured by the current Poisons Standard and is generally considered to be covered by the existing group entry for erythropoietins. Structurally, it is a recombinant human erythropoietin–hyFc fusion protein rather than a conventional erythropoietin, creating uncertainty as to whether it falls within the scope of the current group entry. Accordingly, a change to the current listing is warranted to provide regulatory clarity.

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 broaden the group entry as recommended by the Committee as follows:

Schedule 4 – Amend entry

ERYTHROPOIETIN RECEPTOR AGONISTS ~~ERYTHROPOIETINS~~ **except** when separately specified in these Schedules.

Index – Amend entry

ERYTHROPOIETIN RECEPTOR AGONISTS ~~ERYTHROPOIETINS~~

Schedule 4

Appendix D, clause 5

Cross reference: efepoetin alfa

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

Item	Poison
14	ERYTHROPOIETIN RECEPTOR AGONISTS ~~ERYTHROPOIETINS~~ **except** when separately specified in this Appendix

Materials considered

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

- the proposal to amend the current Poisons Standard with respect to efepoetin alfa (the **Application**)
- the 30 public submissions, received in response to the pre-meeting consultation under regulation 42ZCZK of the Regulations (the **Submissions**)
- the advice received from the 48th 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 SPF, and
- the Handbook.

Summary of Committee advice to the Delegate

The Committee recommended that a new Prescription Only medicine (Schedule 4) group entry and corresponding Appendix D entries for erythropoietin receptor agonists be created in the Poisons Standard to encompass both existing erythropoietins and newer related substances, such as efepoetin alfa, that may not be adequately captured by the current entry.

In relation to scheduling efepoetin alfa, 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:

– Consistent with other erythropoietin receptor agonists, substances within this class pose a risk of serious cardiovascular adverse events, including myocardial infarction, stroke and hypertension.

Benefits:

– At least equally useful to other medicines in treatment of anaemia in chronic kidney disease

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

– Therapeutic use for anaemia in chronic kidney disease

c) the toxicity of a substance

– Limited data but likely no more toxic than other erythropoietin receptor agonists

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

– Packed for injection

e) the potential for abuse of a substance

– Performance image enhancing drugs (PIED). Prohibited by WADA and Sports Integrity Australia.

– Importation prohibited without authority or a prescription

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

– Recommend Schedule 4 and Appendix D group entry for erythropoietin receptor agonists not otherwise scheduled.

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

I have made an interim decision to amend the current Poisons Standard in relation to the group entry for erythropoietins, by broadening the entry to state erythropoietin receptor agonists.

The material considered in making this decision demonstrated that the proposed change would encompass all agents affecting erythropoiesis through similar mechanisms of action, and aligns with categorisation used internationally, such as by the World Anti-Doping Agency.

I have considered the public submissions received during the pre-meeting consultation period, whereby 30 responses were received, comprising 9 responses in support, 2 responses indicating

partial support and 19 responses in opposition. As no reasons were provided by respondents, the weight that can be afforded to these responses is limited. Nevertheless, I note that the consultation responses were, on balance, generally not supportive of the proposed creation of new Schedule 4 and Appendix D, Clause 5 entries for efepoetin alfa.

Efepoetin alfa exhibits similar pharmacological properties to other widely used erythropoietin receptor agonists, whilst a secondary mechanism of action increases the half-life of the medicine, extending its duration of action. Efepoetin alfa was found to be non-inferior to methoxy polyethylene glycol-epoetin beta, a long-acting erythropoiesis-stimulating agent, in correcting anaemia and maintaining haemoglobin levels among stage 3 and 4 chronic kidney disease patients during an open-label Phase 3 trial and exhibited a comparable safety profile.[5]

Like other erythropoietin receptor agonists, efepoetin alfa's potential for misuse as a performance-enhancing drug demonstrates the necessity for tight controls on its supply and possession, to ensure that it is used in a responsible and beneficial manner.

In relation to section 52E(1)(a) and (b) of the Act, I agree with the Committee's statements that the risks and benefits of efepoetin alfa likely align with those of other currently scheduled erythropoietin receptor agonists, such as epoetin alfa and darbepoetin alfa.

With reference to s 52E(1)(c) of the Act, I acknowledge that the toxicity data on efepoetin alfa is limited, but the results yielded from a non-inferiority study demonstrates a similar toxicology profile to other erythropoietin receptor agonists. As such, I am satisfied that the toxicity profile of efepoetin alfa aligns with inclusion in Schedule 4.

Regarding s 52E(1)(e) of the Act, efepoetin alfa holds potential for misuse as it is may be used as a performance enhancing drug. Erythropoietin based constructs, including EPO-Fc proteins, are prohibited by the World Anti-doping Agency (WADA)[4] and Sports Integrity Australia. The inclusion of an Appendix D, Clause 5 entry (possession without authority to be illegal) for efepoetin alfa aims to deter misuse by those who may seek to use the substance for its performance-enhancing capabilities.

I agree with the Committee that the group entry for erythropoietins should be amended to a broader group entry for erythropoietin receptor agonists. However, until such a time that a product is approved for therapeutic use in Australia, I do not consider efepoetin alfa warrants an individual entry in Schedule 4 and Appendix D. While efepoetin alfa is a recombinant human erythropoietin fusion protein that contains a hybrid Fc fragment, I accept it binds to the erythropoietin receptor with high affinity *in vitro.* Therefore, I consider efepoetin alfa is captured under the amended erythropoietin receptor agonists group entry.

Proposed implementation date

1 February 2027

Interim decision in relation to vitamin D

Proposal

The applicant proposed to amend the current Poisons Standard in relation to vitamin D. Under the proposal, vitamin D for human internal therapeutic use would be a Pharmacy medicine (Schedule 2) if it is in divided preparations containing 175 micrograms (7,000 IU) or less of vitamin D per recommended single weekly dose and packaged in primary packs containing no more than 8 dosage units.

All divided preparations containing 175 micrograms or less of vitamin D per recommended single weekly dose are currently Pharmacist only (Schedule 3) medicines irrespective of pack size. Preparations containing 25 micrograms or less per recommended daily dose would continue to be

[4] The Prohibited List | World Anti Doping Agency; <https://www.wada-ama.org/en/prohibited-list?page=1&q=erythro&all=1#search-anchor> (viewed 25 September 2026).

unscheduled, while other therapeutic vitamin D preparations continue to be Prescription only medicines (Schedule 4).

Interim decision

Pursuant to regulation 42ZCZN of the Regulations, the Delegate has, in relation to the proposed amendment, made an interim decision not to amend the current Poisons Standard in relation to vitamin D.

Materials considered

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

- the application to amend the current Poisons Standard with respect to vitamin D (the Application)
- the 46 public submissions, with 6 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 48th 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; and (f) any other matters that the Secretary considers necessary to protect public health
- the SPF, and
- the Handbook.

Summary of Committee advice to the Delegate

The Committee advised that no change be made to the scheduling of vitamin D as the current Poisons Standard entries remains appropriate.

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:

– No or minimal risk at the recommended dose. Risk of toxicity at very large overdose, or chronic toxicity largely through inadvertent daily intake of weekly dosage over a long time - resultant hypercalcaemia and hypercalciuria.

– Inadvertent daily dosing of higher dose weekly-administration products over a long period and/or without supervision can lead to acute toxicity.

– Self-supply may cause patients to neglect routine monitoring of Vitamin D levels in blood.

Benefits:

– Supplementation to prevent deficiency in high-risk populations, and to treat deficiency (dose recommendations vary).

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

– For the prevention of vitamin D deficiency in high-risk populations, or for the treatment of vitamin D deficiency.

c) the toxicity of a substance

– Low risk of genotoxicity, carcinogenicity or reproductive toxicity/teratogenicity at recommended dose.

– Excessive intake of vitamin D can lead to toxicity characterised by hypervitaminosis D, hypercalcaemia, and hyperphosphatemia.

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

– Single weekly dose, 25-175 micrograms, 8 tablet pack.

e) the potential for abuse of a substance

– Nil.

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

– The minimal gain in convenience for access through Schedule 2 versus Schedule 3 is outweighed by the risks.

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

I have made an interim decision not to amend the current Poisons Standard in relation to vitamin D.

The material considered in making this decision did not demonstrate that the proposed change would maintain a level of safety equivalent to that provided under the existing scheduling. The material considered also did not substantiate the Application claim that improved access to weekly dosing would improve consumer adherence or that this benefit would outweigh the safety risks.

I have considered the 46 public submissions received during the pre-meeting consultation period, which included responses from 42 individuals and 4 organisations. Of these, 23 written responses fully supported the applicant's proposal, 2 were partially supportive, and 21 were opposed. Of the 6 responses that included written components, 2 were supportive and 4 were opposed.

Submissions in support of the proposed scheduling expressed the importance of improving access to vitamin D for at-risk groups, such as individuals who avoid sun exposure or use sunscreen and highlighted the role of supplementation in preventing and treating deficiency.

The submissions opposing the proposal raised concerns regarding safety and the appropriateness of the proposed scheduling controls for vitamin D preparations. These submissions noted that classification as a Pharmacy medicines (Schedule 2) allows supply of products where professional support is available upon request but not required as for Pharmacist only medicines (Schedule 3). Concerns were raised that this may increase the likelihood of dosing errors, particularly for higher-strength formulations intended for weekly administration that could be mistakenly taken daily. While smaller pack sizes may limit the duration of exposure associated with such errors, concerns remained that labelling, packaging and presentation alone may not adequately mitigate the risk of repeated or

chronic overexposure. Furthermore, classification in Schedule 2 would limit potential for intervention at point of repeat purchase where dosing instructions have been misunderstood.

The submissions noted that consumers are generally unable to self-assess vitamin D deficiency or monitor treatment effectiveness without clinical assessment and pathology testing. Submitters acknowledged that vitamin D deficiency is common in the Australian population, but that vitamin D deficiency is usually asymptomatic and routine screening of healthy people with no risk factors for vitamin D deficiency is not recommended, nor is treatment for cases of mild deficiency without symptoms or other complications. Submitters argued that the safe and effective use of once-weekly vitamin D products may require professional advice regarding appropriate dosing and the avoidance of medication errors. It was therefore contended that the higher-strength vitamin D products do not fully align with the factors for Schedule 2 medicines and would be more appropriately supplied as Schedule 3 medicines, where pharmacist intervention at the time of supply provides an important risk-mitigation measure.

Further concerns regarding the potential for harms associated with dosing errors of higher-strength vitamin D products intended for weekly administration addressed the risks of vitamin D toxicity. Submitters referred to published international reports of vitamin D toxicity, including cases of severe hypercalcaemia and other serious adverse outcomes associated with overdosing and administration errors, and manufacturing or labelling errors.[5,6,7,8,9]

I agree with the Committee's conclusions on the relevant provisions of section 52E of the Act. I agree that the principal concern associated with the proposal is the potential for vitamin D toxicity, as a result of possible dosing errors or inappropriate self-selection of high-strength weekly preparations. Weekly-dose products may be particularly susceptible to administration errors where a once-weekly dose is inadvertently taken daily, resulting in overexposure and an increased risk of vitamin D toxicity. Additionally, vitamin D requirements vary according to age, skin pigmentation, sun exposure, and comorbid conditions, rendering universal self-selection inappropriate, as deficiency may not have been confirmed or require treatment. Furthermore, while smaller pack sizes may reduce the duration of exposure if a dosing error were to occur, they do not prevent repeated purchases and the potential for chronic overdosing. I also agree with the Committee that the Prescription Only medicines (Schedule 4) entry for vitamin D remains appropriate.

I have considered international regulatory approaches to higher-dose vitamin D preparations. While regulatory arrangements vary between jurisdictions, several countries, such as New Zealand[10], Canada[11] and Singapore[12], maintain additional controls over higher-strength vitamin D products through prescription-only supply or other forms of health professional oversight. In my view, these approaches recognise that higher-strength vitamin D preparations present a different risk profile from lower-strength preparations used for routine supplementation. This is consistent with the current Australian scheduling framework, which provides for a graduated level of access, with higher-strength weekly-dose preparations remaining subject to pharmacist involvement at the point of supply as

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[5] Stafford N. *Vitamin D supplements poison dozens of Danish children*. BMJ. 2016;354: i4534. https://doi.org/10.1136/bmj.i4534.

[6] Virú-Loza MA, Alvarado-Gamarra G, Zapata-Sequeiros RI, Flores-Nakandakare HF. *Life-threatening hypercalcemia in a child with vitamin D intoxication due to parental self-medication: A case report*. SAGE Open Med Case Rep. 2024;12. https://doi.10.1177/2050313X241269560.

[7] Levita J, Wilar G, Wahyuni I, et al. *Clinical Toxicology of Vitamin D in Pediatrics: A Review and Case Reports*. Toxics. 2023;11(7). https://doi.org/10.3390/toxics11070642.

[8] O'Brien M, Koh E, Barsh GR, et al. *Posterior Reversible Encephalopathy Syndrome Due to Vitamin D Toxicity*. Pediatrics. 2024;154(4). https://doi.org/10.1542/peds.2024-067126.

[9] Araki T, Holick MF, Alfonso BD, et al. *Vitamin D intoxication with severe hypercalcemia due to manufacturing and labeling errors of two dietary supplements made in the United States*. J Clin Endocrinol Metab. 2011;96(12):3603-3608. https://doi.org/10.1210/jc.2011-1443.

[10] https://consult.health.govt.nz/medsafe/vitamin-d-classification/supporting_documents/vitamin-d-consultation-2026-information-questionspdf. Accessed September 2026

[11] https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/prescription-drug-list/notices-changes/notice-amendment-vitamin-d.html. Accessed September 2026.

[12] Health Sciences Authority Singapore. *Proper vitamin and mineral supplementation*; HealthHub Singapore. *Vitamin D Medication Information Leaflet*; and Keystone Clinic & Surgery. *Teleconsultation for Prescription Vitamins*. Accessed September 2026.

labelling, packaging and presentation of the higher-strength product is considered insufficient to mitigate the risks of inappropriate use or accidental vitamin D overdose.

In relation to section 52E(1)(a), (b) and (c) of the Act, I have considered that vitamin D supplementation may provide significant health benefits for individuals susceptible to or with a deficiency. Supplementation is an established treatment for moderate to severe vitamin D deficiency and associated skeletal complications, including osteomalacia. However, inappropriate or excessive oral intake may result in vitamin D toxicity; generally accepted as serum 25-hydroxyvitamin D concentrations above 150 ng/mL.[13] The principal consequence of vitamin D toxicity is hypercalcaemia, which may cause symptoms such as nausea, vomiting, constipation, polydipsia, polyuria, dehydration, muscle weakness and neuropsychiatric effects including confusion and lethargy.[14] In more severe cases, persistent hypercalcaemia can result in renal impairment, cardiac arrhythmias and other serious complications requiring medical intervention.[15]

With respect to section 52E(1)(d) of the Act, concerns remained that labelling, packaging and presentation alone may not adequately mitigate the risk of repeated or chronic vitamin D overexposure.

With respect to section 52E(1)(e) of the Act, I acknowledge that vitamin D has no recognised potential for abuse.

Having considered the Application, the Submissions, the Committee's advice, and the matters set out in section 52E of the Act, as well as international regulatory approaches, I am not satisfied that a case has been established for amending the current scheduling for vitamin D. While vitamin D deficiency is common in the Australian population, consumers are generally unable to self-assess vitamin D deficiency or monitor treatment effectiveness without clinical assessment and pathology testing. I consider that the current Pharmacist Only medicine (Schedule 3) classification for weekly-dose vitamin D preparations remains appropriate as the evidence indicates that higher-strength weekly-dose products present a greater risk of dosing error and toxicity than lower-dose preparations intended for routine supplementation. While the proposed Pharmacy medicine (Schedule 2) entry may improve dosing convenience for some consumers, I am not satisfied that this benefit outweighs the risks of vitamin D toxicity which may occur with reduction in pharmacist oversight. Furthermore, I am not satisfied the toxicity risks can be mitigated through labelling, packaging, or the presentation of high-strength vitamin D products. Accordingly, I consider that the existing scheduling framework continues to provide the most appropriate for the safe use of vitamin D products.

My interim decision is that no amendment be made to the current Poisons Standard in relation to vitamin D.

[13] Nowson CA, McGrath JJ, Ebeling PR, et al. *Working Group of Australian and New Zealand Bone and Mineral Society, Endocrine Society of Australia and Osteoporosis Australia. Vitamin D and health in adults in Australia and New Zealand: a position statement*. Med J Aust. 2012 Jun 18;196(11):686-7. doi: 10.5694/mja11.10301.

[14] Walker MD, Shane E. *Hypercalcemia: A Review*. JAMA. 2022 Oct 25;328(16):1624-1636. doi: 10.1001/jama.2022.18331.

[15] Walker MD, Shane E; 2022. (*see footnote 13*).

Interim decisions on proposed amendments referred to the Advisory Committees on Medicines and Chemicals Scheduling in joint session (ACMS-ACCS #42)

Interim decision in relation to hydroquinone

Proposal

The Department of Health, Disability and Ageing has proposed deleting the Pharmacy medicine (Schedule 2) entry in the current Poisons Standard for hydroquinone. Under the proposal all human external therapeutic or cosmetic use preparations of hydroquinone would be captured under the existing Prescription only medicine (Schedule 4) entry.

Hair preparations containing 0.3% or less hydroquinone and nail preparations containing 0.02% or less of hydroquinone will continue to be exempted from scheduling.

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 hydroquinone as below.

The Pharmacy only (Schedule 2) entry would be deleted with the creation of a new Pharmacist only medicine (Schedule 3) entry for hydroquinone, specific to use in hyperpigmentation. The current entries in Prescription only medicine (Schedule 4) and Poisons (Schedule 6) of the Poisons Standard would be amended as follows:

~~**Schedule 2 – Delete entry**~~

~~HYDROQUINONE (excluding monobenzone and alkyl ethers of hydroquinone included in Schedule 4) in preparations for human external therapeutic or cosmetic use for hyperpigmentation containing 2% or less of hydroquinone except:~~

~~a) in hair preparations containing 0.3% or less of hydroquinone; or~~
~~b) in cosmetic nail preparations containing 0.02% or less of hydroquinone.~~

Schedule 3 – New entry

HYDROQUINONE (excluding monobenzone and alkyl ethers of hydroquinone included in Schedule 4) in preparations for human external therapeutic or cosmetic use for hyperpigmentation containing 2% or less of hydroquinone except:

a) in hair preparations containing 0.3% or less of hydroquinone; or
b) in cosmetic nail preparations containing 0.02% or less of hydroquinone.

Schedule 4 – Amend entry

HYDROQUINONE (other than its alkyl ethers separately specified in this Schedule) in preparations for human therapeutic or cosmetic use except:

when included in Schedule ~~2~~ 3; or

a) in hair preparations containing 0.3% or less of hydroquinone; or
b) in cosmetic nail preparations containing 0.02% or less of hydroquinone.

Schedule 6 – Amend entry

HYDROQUINONE **except**:

when included or expressly excluded from in Schedule ~~2~~ 3or 4; or in preparations containing 10% or less of hydroquinone.

Index – New entry

HYDROQUINONE
cross reference: ARBUTIN, GLYCOSYLATED HYDROQUINONE, MONOBENZONE

Schedule 6

Schedule 4

~~Schedule 2~~

Schedule 3

Appendix E, clause 3

Appendix F, clause 4

The Committee also recommended to amend the Appendix E and F entries and create a new Appendix H entry for hydroquinone in the Poisons Standard as follows:

Appendix E, Clause 3 – Poisons that must be labelled with first aid instructions

Item	Poison	Standard statement for first aid instruction
~~152~~	~~HYDROQUINONE—when included in Schedule 2~~	~~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).~~
153	HYDROQUINONE—when included in Schedule 3, 4 or 6	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). G2 – If swallowed, give activated charcoal if instructed. 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. R2– If swallowed or inhaled, remove from contaminated area. Apply artificial respiration if not breathing. Do not give direct mouth-to-mouth resuscitation. To protect rescuer, use air-viva, oxy-viva or one-way mask. Resuscitate in a well-ventilated area. S1– If skin or hair contact occurs, remove contaminated clothing and flush skin and hair with running water.

Appendix F, Clause 4 - Poisons that must be labelled with warning statements and safety directions

Item	Poison	Warning statements and Safety directions
176	HYDROQUINONE—when included in Schedule ~~2~~ 3	45 WARNING – If a pigmented spot or mole has recently become darker, changed colour, become enlarged or itchy, or bleeds, do not use this product, see your doctor immediately. Do not use on children. Do not use near the eyes. Mild irritation may occur; stop use if it becomes severe. If fading is not evident in three months, seek doctor's advice. Do not exceed recommended dose. Excessive or prolonged use should be avoided because darkening of the skin can occur.

177	HYDROQUINONE—except when included in Schedule 3 or ~~2 or~~ 4	1 – Avoid contact with eyes. 4 – Avoid contact with skin.

Appendix H, Clause 1 - Schedule 3 medicines permitted to be advertised

Item	Poison
23	HYDROQUINONE

Materials considered

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

- the application to amend the current Poisons Standard with respect to hydroquinone (the Application)
- the 94 public submissions received in response to the pre-meeting consultation under regulation 42ZCZK of the Regulations (the Submissions)
- The advice received from the 42nd meeting of the Advisory Committee on Medicines and Chemicals Scheduling in joint session (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 SPF, and
- the Handbook.

Summary of Committee advice to the Delegate

The Committee recommended that a new Pharmacist only medicine (Schedule 3) entry for hydroquinone be created to replace the current Schedule 2 entry and the entries in Prescription only medicine (Schedule 4) and Poisons (Schedule 6) of the Poisons Standard be amended. The interim decision reflects the advice provided by the Committee.

Accordingly, all human external therapeutic or cosmetic use preparations of hydroquinone would be captured under the existing Schedule 3 entry. Cosmetic preparations for hair (containing 0.3% or less hydroquinone) and nail (containing 0.02% or less hydroquinone) will continue to be exempted from scheduling.

The Committee suggested an implementation date of 6 months from the final decision to provide sufficient time for industry to register Product Information (PI) and Consumer Medicine Information (CMI) documents in Australia.

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:

- Skin rashes, facial swelling, permanent skin discoloration including exogenous ochronosis, transient erythema, mild burning sensation, hypersensitivity, irritation, allergic contact dermatitis, inflammation, xeroderma
- Theoretical risk of kidney cancer (The International Agency for Research on Cancer (IARC) has listed hydroquinone as a group 3 substance that is not classifiable as carcinogenic to humans)

Benefits:

- Use for hyperpigmentation is effective
- First-line treatment for several hyperpigmentation conditions, including: melasma, chloasma, age spots, proinflammatory hyperpigmentation caused by acne or trauma

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

- First-line treatment for several hyperpigmentation conditions
- Cosmetic products (e.g. hair dye, artificial nail products, skin lightening products)

c) the toxicity of a substance

- Animal studies show carcinogenic effects of oral hydroquinone (hepatic and renal adenomas, leukemia) at high doses.
- No systemic toxicity but low acute dermal toxicity observed in animal studies
- Not considered to have reproductive or developmental toxicity
- Acute toxicity – category 4: H302 (Harmful if swallowed)
- Carcinogenicity – category 2: H351 (Suspected of causing cancer)
- Germ cell mutagenicity – category 2: H341 (Suspected of causing genetic defects)
- Eye damage – category 1: H318 (Causes serious eye damage)
- Skin sensitisation – category 1: H317 (May cause an allergic skin reaction)

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

- Hydroquinone is available as a cream, emulsion, gel, or solution
- Six creams containing hydroquinone 2% as an active ingredient are currently active and listed in the ARTG, including three export-only products and three non-prescription products

e) the potential for abuse of a substance

- Use over the entire body or for prolonged periods may pose an unacceptable risk of adverse outcomes

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

- Alignment of Australian regulations for skin lightening preparations with the EU and US.

- In September 2020, the FDA announced a ban on all over-the-counter topical products containing hydroquinone and has required existing products to be removed from the marketplace
- International changes have seen over the counter skin lightening products banned from some EU markets as well

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

I have made an interim decision to amend the Schedule 2, 3, 4, and 6 entries with regards to hydroquinone.

The material considered in making this decision demonstrated that the proposed change may reduce risks of inappropriate access and use of ≤2% hydroquinone as broad skin lightening treatment through pharmacist oversight and advice within a Schedule 3 entry.

I have considered the 94 public submissions received during the pre-meeting consultation period which made an indication of support or opposition for the proposal; 35 of which were supportive, 4 were partially supportive and 55 opposed the proposal. Overall, 16 submitters provided written justifications addressing the proposed deletion of the Schedule 2 entry for hydroquinone. Of these 16, 3 supported the proposal, 1 partially supported it and 12 opposed it.

Supportive submissions highlighted that the proposed amendment would reduce inappropriate access to hydroquinone and the risks associated with prolonged exposure or misuse as a skin lightening treatment. Several submissions highlighted the risk of irreversible exogenous ochronosis from prolonged or incorrect use, although it is acknowledged that this has be more commonly associated with concentrations ≥ 2% hydroquinone.

Several submissions suggested deleting the current Schedule 2 entry of hydroquinone and creating a new entry to Schedule 3 rather than Schedule 4. It was suggested that this would mitigate risk by ensuring pharmacist oversight of supply and engagement with consumers. Furthermore, therapeutic need could be assessed at the point of sale and appropriate information provided on usage, warnings, and guidance. It was noted that treatment guidelines to assist pharmacists could be provided through an update to include hydroquinone in the Australian Pharmaceutical Formulary and Handbook. Additionally, it was noted that pharmacist intervention under Schedule 3 would reduce unnecessary burden, in comparison to the proposed deletion of the Schedule 2 entry, on medical practitioners, such as general practitioners and dermatologists, for a low-risk treatment of hyperpigmentation.

Some submissions raised concerns regarding pharmacist-led prescribing; highlighting their lack of diagnostic training in skin conditions, the risk of misdiagnosis of a more serious ailment (e.g. failure to identify melanoma or underlying causes), limitations in assessing contraindications, such as pregnancy, and insufficient follow-up. Respondents stressed that pigmentation disorders are complex and require specialist assessment. The submissions argued that oversight by appropriately trained medical professionals, particularly dermatologists, was required as their skills enable both treatment of hyperpigmentation and management of any complications which may arise from use of hydroquinone. I acknowledge this is supported by the Schedule 4 entry which requires prescription for higher concentration hydroquinone products. Deleting the current Schedule 2 entry and creating a new one in Schedule 3, will also increase oversight by a healthcare professional. I note, the Pharmacy Guild supported the creation of a Schedule 3 entry.

Finally, one submission highlighted that heavily restricting access may result in consumers seeking unsafe alternatives. Some submissions considered the initial proposal excessive given the hydroquinone's established safety profile at low (≤2%) concentration. Instead, the submission provided a recommendation to retain the Schedule 2 classification, with added restrictions limiting use to topical treatments for hyperpigmentation. This was considered by the respondent to maintain access while ensuring appropriate safeguards. I do not believe the benefit of introducing a restriction to use for hyperpigmentation alone is adequate to appropriately safeguard risks.

I have considered international regulatory approaches. The US does not permit over the counter skin products containing hydroquinone unless approved by the FDA, and currently 1 prescription only

topical 4% hydroquinone product is approved. While in the EU and Association of Southeast Asian Nations (ASEAN) countries, hydroquinone in cosmetic products is not permitted, except 0.02% for artificial nail systems. New Zealand also requires pharmacy only sale of external use 2% hydroquinone. One submission which did not entirely oppose the original proposal acknowledged that the intention of the proposal is to align with EU and US international regulations but suggested that the revised entries should explicitly exclude all hydroquinone derivatives not otherwise scheduled to enhance clarity. However, it is noted that many hydroquinone derivatives are appropriately captured under existing entries for similar chemicals, such as arbutin or monobenzone.

I agree with the Committee's findings on the relevant provisions of section 52E of the Act and the recommendation to create a new Appendix H entry for hydroquinone. Furthermore, I agree with the Committee's view that the complexity of pigmentation disorders and risk management supports oversight by appropriately trained medical professionals, particularly dermatologists. I note the Committee acknowledged that there were likely cultural and social factors influencing skin-lightening practices, alongside concerns about online sales circumventing pharmacy oversight. I also accept that overly strict restrictions may reduce access and drive unsafe use, highlighting the need for a balanced, well-regulated approach that ensures safety while maintaining appropriate consumer access. The Committee surmised that clear labelling, warnings, and comprehensive product information should be required for all hydroquinone-containing products. Furthermore, the Committee highlighted that online sales loopholes should be addressed to prevent inappropriate access; however, these matters are beyond the remit of scheduling.

In considering s 52E(1)(a), (b) and (e) of the Act, I note that hydroquinone is potent and effective for treating hyperpigmentation and used in cosmetic products with other uses (e.g. hair dye and artificial nail products) with a well-established safety profile. Hydroquinone products in Australia are commonly used to treat hyperpigmentation conditions like melasma, post-inflammatory hyperpigmentation, and other disorders involving skin discoloration. Hydroquinone should be used on small, targeted areas, and not for general skin lightening. However, concerns have been raised that there is a risk of misuse of hydroquinone as a cosmetic skin lightening product which may increase the risks of harms where it is used over large portions of the body and for prolonged periods of time. Use of this nature may increase the risks of harms and toxicity. Other key concerns related to hydroquinone scheduling include misdiagnosis of underlying conditions (including serious diseases like melanoma), inappropriate prescribing or instructions and a possible lack of monitoring.

Regarding s 52E(1)(c) of the Act, I am satisfied that there have been case reports of leukoderma (localised loss of pigmentation of the skin) and ochronosis (permanent bluish black discolouration of tissues) from using hydroquinone creams containing 2% of the chemical.[16] Other risks from low concentration hydroquinone products include skin irritation, potential worsening of pigmentation, and allergic contact dermatitis. Hydroquinone is also known to cause serious damage on eye contact. There is inadequate evidence in humans for the carcinogenicity of hydroquinone, however, there is limited evidence in laboratory animals, and hydroquinone is not considered to have reproductive or developmental toxicity.

In relation to s 52E(1)(d) of the Act, I note that 6 hydroquinone products are currently active on the Australian Register of Therapeutic Goods (ARTG). All are 2% cream formulations, including 3 export-only products and 3 non-prescription products. The Therapeutic Goods (Medicines Advisory Statements) Specification 2021 also defines a number of labelling requirements for hydroquinone products which are within the current Schedule 2 entry. This decision maintains the labelling requirements in Appendix E and F.

On the basis of the above considerations, I have decided to amend the entries consistent with the Committee's advice, and I have decided on an implementation date for 12 months following the final decision publication to provide sufficient time for industry to comply with the amendment and register Product Information (PI) and Consumer Medicine Information (CMI) documents in Australia.

Proposed implementation date

1 February 2028

[16] https://www.industrialchemicals.gov.au/sites/default/files/1%2C4.

Interim decision on proposed amendments referred to the Advisory Committee on Chemicals Scheduling (ACCS #41, November 2025)

Interim decision in relation to oxalic acid

Proposal

The proposal is to amend the current Poison Standard with regards to the Poison (Schedule 6) entry for oxalic acid to exempt commercial, household or domestic cleaning products, containing 9.5% or less of soluble salts of oxalic acid. Under the proposal, such products would be available without the POISON signal heading and without the first aid instructions, warning statements and general safety directions currently applicable to them.

Interim decision

Pursuant to regulation 42ZCZN of the Regulations, the Delegate has made an interim decision to not amend the current Poisons Standard in relation to oxalic acid.

Materials considered

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

- the application to amend the current Poisons Standard with respect to oxalic acid (the **Application**)
- the 32 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 41st meeting of the Advisory Committee on Chemicals 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 SPF, and
- the Handbook.

Summary of Committee advice to the Delegate

The Committee recommended that no change should be made to the current Poisons Standard in relation to oxalic acid.

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:

- Toxicity risk from oral, dermal, ocular and inhalation exposure.
- pH <2 poses caustic risk.
- Corrosive effects can still occur at concentrations less than 10%. There have been documented injuries and there are concerns regarding a potential lack of child-resistant packaging.

Benefits:

- Well-established cleaning applications, particularly in rust removal and timber cleaning across domestic, household, and commercial environments.

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

- Widely used internationally in cleaning applications.
- Commonly available in Australia for rust and wood cleaning applications.
- Emerging use as in pesticides by the bee industry. This involves application to hive in liquid or vapour form.

c) the toxicity of a substance

- Moderate risk of acute oral toxicity (at the proposed thresholds).
- Corrosive to skin, eyes, and respiratory tract.
- NSW Poisons Information Centre data indicates injury can occur at less than 10%.
- Known nephrotoxin

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

- Wide range of domestic cleaning formulations, internationally products range up to 20% of oxalic acid.
- Products are often well-packaged, but an exemption from scheduling would remove any requirement for mandatory warnings.

e) the potential for abuse of a substance

- Nil.

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

- Industrial use for Varroa mite control in beehives. Currently, the Australian Pesticides and Veterinary Medicines Authority (APVMA) has issued an emergent permit to NSW Department of Primary Industries for an unregistered product. (Api-Bioxal (oxalic acid) / European honeybee / Varroa mite).

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

I have made an interim decision not to amend the Poisons Standard in relation to oxalic acid as proposed by the applicant. In making my decision, I have provided detailed reasons below.

Oxalic acid is an organic compound naturally present in a wide range of foods with typical dietary intake ranging from 5–500 mg per day. It is also produced endogenously by humans as a metabolic product with approximately 30–70% of endogenous oxalic acid excreted daily, primarily in urine. Oxalates (soluble and insoluble forms) are widespread in plants and herbal medicines, as well as widely used in laboratories and in sanitisation, fumigation (bee keeping), etching and descaling, and removing mineral deposits in industrial and household cleaning applications.

I have considered the 32 public submissions received during the pre-meeting consultation period. Five of the submissions were supportive, with 1 providing a written response; 5 partially supported the proposal with 2 of these providing written justification; while 22 submissions opposed the proposal and only 1 of these provided a written response.

One submission, which partially supported the proposal, raised the concerns that about the current entry for oxalic acid in Schedule 6 does not exclude soluble oxalate salts, despite these salts having their own individual entries in Prescription only medicines (Schedule 4). The submission argues that preparations for therapeutic use containing oxalic acid, in particular those including soluble oxalate salts, need to be excluded from the Schedule 6 entry to prevent their unintended capture in listed medicines on the ARTG. However, substances with soluble oxalates, for example escitalopram, are Schedule 4 medicines and registered products and there has not been any reported lack of clarity or confusion to the Scheduling status of these medicines. Schedule 4 is more restrictive than Schedule 6 in the Poisons Standard; the exception clause in the Schedule 6 entry is not required.

In relation to s 52E(1)(a), (b), (d) and (f) of the Act, I noted the substances are widely used in well-established cleaning applications particularly in rust removal and timber cleaning across domestic, household, and commercial environments.

A wide range of domestic cleaning formulations are available internationally, ranging in concentrations up to 20% of oxalic acid. I acknowledge existing products are often well-packaged, but an exemption from scheduling would remove any requirement for mandatory warnings.

An emerging use of oxalic acid is as a pesticide within the apiculture sector including application to hives in liquid or vapour form. In this regard, the Australian Pesticides and Veterinary Medicines Authority has issued an emergency permit to NSW DPI for the use of an unregistered product (Api-Bioxal) for the control of *Varroa* mite in European honeybees.

Regarding s 52E(1)(a) and (c) of the Act, I note that evidence indicates corrosive effects have been identified at concentrations below 10%. Information provided by the NSW Poisons Information Centre further indicates documented injuries occurring at concentrations lower than 10%. Under the applicant's proposal, products containing 9.5% or less of soluble salts of oxalic acid would be unscheduled and therefore available without a POISON signal heading, child resistant packaging (currently applicable requirements), first aid instructions, warning statements, or safety directions. The removal of these established risk mitigation measures would increase the potential of harm and elevate the overall risk to public health.

The proposed exemption threshold appears to be based on making available an existing product formulation currently available in some overseas markets, rather than on toxicity data and risks to consumers. I agree with the Committee's concern regarding the lack of sufficient evidence to justify either 9.5% (application) or 10% (submission) as an appropriate cut-off for exemption of oxalic acid in commercial, household or domestic cleaning products.

On the basis of the above considerations, I agree with the Committee's view that compelling evidence has not been provided to support the amendment of the current scheduling, but identified several risks associated with the proposed change. I have decided not to amend the current Poisons Standard.

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