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

Consultation: Proposed amendments to the Poisons Standard – ACMS #48, ACCS #41 and Joint ACMS-ACCS #42 meetings, November 2025

18 September 2025

Confidentiality

All submissions received will be placed on the TGA's Internet site, unless marked confidential. Any confidential material contained within your submission should be provided under a separate cover and clearly marked "IN CONFIDENCE". Reasons for a claim to confidentiality must be included in the space provided on the TGA submission form. For submission made by individuals, all personal details, other than your name, will be removed from your submission before it is published on the TGA's Internet site. In addition, a list of parties making submissions will be published. If you do not wish to be identified with your submission you must specifically request this in the space provided on the submission form.

Contents

About this consultation

Subdivision 3D.2 of the Therapeutic Goods Regulations 1990 (the Regulations) sets out the procedure to be followed where the Secretary receives an application under section 52EAA of the Therapeutic Goods Act 1989 (the Act) to amend the current Poisons Standard or decides to amend the Poisons Standard on his or her own initiative and decides to refer the proposed amendment to an expert advisory committee. These include, under regulation 42ZCZK, that the Secretary publish (in a manner the Secretary considers appropriate) the proposed amendment to be referred to an expert advisory committee, the committee to which the proposed amendment will be referred, and the date of the committee meeting. The Secretary must also invite public submissions to be made to the expert advisory committee by a date mentioned in the notice as the closing date, allowing at least 20 business days after publication of the notice.

In accordance with regulation 42ZCZK of the Regulations, the Secretary invites public submissions on scheduling proposals referred to the November 2025 meetings of the Advisory Committee on Medicines Scheduling (ACMS #48), Advisory Committee on Chemicals Scheduling (ACCS #41) and Joint Advisory Committees on Medicines and Chemicals Scheduling (Joint ACMS-ACCS #42). Submissions must be received by close of business 17 October 2025.

Submissions should be provided through our consultation hub. Any submission about any of the proposals to amend the Poisons Standard will be considered at the next meeting of the Advisory Committee on Medicines Scheduling (ACMS), meeting of the Advisory Committee on Chemicals Scheduling (ACCS), or a joint meeting of these two committees.

This consultation closes on 17 October 2025.

We aim to provide documents in an accessible format. If you're having problems using this document, please contact medicines.scheduling@health.gov.au.

1 Proposed amendment referred for scheduling advice to ACMS meeting #48

1.1 Vitamin D

Proposal

The applicant has 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 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 unscheduled.

CAS number

Vitamin D2: 50-14-6

Vitamin D3: 67-97-0

Alternative names

Vitamin D2: Ergocalciferol

Vitamin D3: Cholecalciferol, colecalciferol

Applicant

Private applicant.

Proposed Scheduling

Vitamin D is currently listed in Schedule 4 and Schedule 3 and is cross-referenced to colecalciferol and ergocalciferol. Vitamin D is also included in Appendix H, clause 1 (Schedule 3 medicines permitted to be advertised).

Schedule 4

VITAMIN D for human internal therapeutic use **except:**

(a) in preparations containing 25 micrograms or less of vitamin D per recommended daily dose; or

(b) when included in Schedule 3.

Schedule 3

VITAMIN D for human internal therapeutic use in preparations containing 175 micrograms or less of vitamin D per recommended single weekly dose **except** in preparations containing 25 micrograms or less of vitamin D per recommended daily dose.

The applicant's proposed amendments to the Poisons Standard are:[1]

Schedule 4 – Amend entry

VITAMIN D for human internal therapeutic use **except**:

(a) in preparations containing 25 micrograms or less of vitamin D per recommended daily dose; or

(b) when included in Schedule 2 or Schedule 3.

Schedule 3 – Amend entry

VITAMIN D for human internal therapeutic use in preparations containing 175 micrograms or less of vitamin D per recommended single weekly dose **except:**

(a) in preparations containing 25 micrograms or less of vitamin D per recommended daily dose; or

(b) when included in Schedule 2.

Schedule 2 – New Entry

VITAMIN D for human internal therapeutic use in divided preparations containing 175 micrograms or less of vitamin D per recommended single weekly dose in primary packs containing no more than 8 dosage units per pack **except** in preparations containing 25 micrograms or less of vitamin D per recommended daily dose.

Index

VITAMIN D

Cross reference: COLECALCIFEROL, ERGOCALCIFEROL

Schedule 4

Schedule 3

Schedule 2

Appendix H, Clause 3.

Background

Vitamin D is a fat-soluble vitamin in two main forms: D2 (ergocalciferol), found in fungi and plants, and D3 (cholecalciferol), sourced from animal products or generated in the skin by sunlight. Vitamin D3 is a more commonly used supplement than vitamin D2, as it has a longer half-life and greater potency, resulting in two to three times more storage in the body.

Supplementation with vitamin D can mitigate the risk of acute respiratory infections, osteomalacia, cardiovascular disease, cancer, sarcopenia, diabetes, multiple sclerosis, osteoarthritis, epilepsy, and cognitive dysfunction.

Although vitamin D supplementation has several benefits, inappropriate or excessive intake can result in vitamin D intoxication. This condition typically arises when serum 25-hydroxyvitamin D levels exceed 100-150 ng/mL. Vitamin D toxicity is rarely caused by prolonged sunlight exposure, as the skin naturally regulates its production by converting excess precursors into inactive metabolites.

The most common clinical manifestations of acute vitamin D intoxication are linked to elevated calcium levels, leading to hypercalciuria and hypercalcemia. Symptoms can include confusion, polydipsia, polyuria, loss of appetite, vomiting, and muscle weakness. Prolonged excessive vitamin D intake can lead to chronic toxicity, which may cause nephrocalcinosis, bone demineralisation, and ongoing pain.

[1] 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.

Summary of applicant's reasons for the proposal

Vitamin D deficiency poses health risks across all life stages from rickets and growth delays in infants to increased fracture and fall risk in older adults.

The 2011-12 National Health Measures Survey (NHMS) shows around 23% of Australian adults, approximately 4 million people, had vitamin D deficiency, with similar rates across genders. Supplement users had significantly lower deficiency rates (7%) than non-users (23%), and about 10% of those with high levels (≥100 nmol/L) were taking supplements.

According to the Tasmanian Government (Nov 2024), supplementation is recommended to prevent and treat deficiency, especially in individuals with limited sun exposure, darker skin, BMI greater than 30 kg/m^2, certain health conditions, or breastfeeding mothers. It plays a key role in preventing related diseases and supporting overall health.

A proposed Schedule 2 pack of 8 dosage units each containing 175 micrograms of vitamin D offers a convenient weekly dose over a two-month period. In contrast, the daily dosing of 25 micrograms requires 60 units over the same timeframe. The change is expected to improve patient experience by reducing dose frequency by 87%, enhancing adherence, and benefiting individuals with swallowing difficulties.

The product could be made available directly from pharmacy shelves, expanding access beyond its current Schedule 3 status, thereby supporting the prevention and treatment of vitamin D deficiency.

Key uses/expected use

Medicine.

Australian regulations

- According to the TGA Ingredient Database,
  - vitamin D2 and D3 is available for use as an active ingredient in: Biologicals, Export Only, Listed Medicines, Over the Counter, Prescription Medicines.
  - both are not available as a Homoeopathic Ingredient in Listed Medicines.
  - both are available for use as an Excipient Ingredient in: Biologicals, Devices, Listed Medicines, Prescription Medicines while vitamin D3 is also available as Excipient Ingredient in Export Only and Over the Counter medicines.
  - only vitamin D3 is available for use as an Equivalent Ingredient in: Listed Medicines, Prescription Medicines.
- As of 15 September 2025, there were 1,823 medicines the Australian Register of Therapeutic Goods (ARTG) that contain colecalciferol as an active ingredient. These include 12 prescription and 1,597 non-prescription medicines available in Australia. In addition, there were 11 medicines that contain ergocalciferol as an active ingredient of which 2 are prescription medicines and 7 are listed medicines.
- According to the Therapeutic Goods (Permissible Ingredients) Determination No. 2 of 2025, Vitamin D is permitted to be included in listed medicines as follows.

Item	Ingredient name	Purpose	Specific requirements
1535	COLECALCIFEROL	A, E	When for internal use, the maximum recommended daily dose must not be more than 25 micrograms of Vitamin D.
2028	ERGOCALCIFEROL	A, E	When for internal use, the maximum recommended daily dose must be no more than 25 micrograms of Vitamin D.

Item	Ingredient name	Purpose	Specific requirements
A = active ingredient for a medicine has the same meaning as in the Regulations E = excipient for a medicine meaning an ingredient that is not an active ingredient or a homoeopathic preparation ingredient			

- The Therapeutic Goods (Permissible Ingredients) Determination No. 2 of 2025 also provides that:
  - vitamin D analogue calcifediol must not be used in medicines with ergocalciferol or colecalciferol
  - vitamin D is a mandatory component for cod liver oil, halibut liver oil, natural fish oil, pollack liver oil, shark liver oil, and skipjack liver oil. For internal use medicines, these fish oils must not supply more than 25 micrograms of vitamin D per maximum recommended daily dose.
- The TGA prescribing medicines in pregnancy database does not include vitamin D.
- There are no warning statements pertaining to vitamin D in the Therapeutic Goods (Medicines Advisory Statements) Specification 2021.
- Since 1971, there have been 1,772 reports of adverse events (including 15 deaths) for products containing colecalciferol as an active ingredient on the Database of Adverse Event Notifications (DAEN) (accessed 15 September 2025). For 1,485 reports there were a single suspected medicine containing colecalciferol. For ergocalciferol, 54 cases were reported of which there were 16 cases where ergocalciferol containing medicines were singly suspected, and there was one reported death from an ergocalciferol containing medicine.
- As of 15 September 2025, there were 23 products containing vitamin D as an active ingredient listed in the Public Chemical Registration Information System Search (PubCRIS) of which 18 are registered products.
- In 2009-19 no adverse events for humans and 3 adverse events for animals were recorded for vitamin D3 (cholecalciferol) in the APVMA Adverse Experience Reporting Program database. There were no reports for vitamin D2 (ergocalciferol).
- Vitamin D3 (cholecalciferol) is listed on the Australian Inventory of Industrial Chemicals, but vitamin D2 (ergocalciferol) is not. However, vitamin D is listed without a specified formula. However, the National Industrial Chemicals Notification and Assessment Scheme (now Australian Industrial Chemicals Introduction Scheme) published a Human Health Tier II Assessment of Calciferols which included both vitamin D2 and D3.

International regulations

- The Health Canada Drug Product Database lists 16 approved products containing vitamin D including 12 for human use (one non-prescription and 11 prescription and 4 for veterinary use (all non-prescription).
- The New Zealand Medsafe Medicines Classification Database classifies colecalciferol medicines as prescription-only when the daily dose exceeds 25 micrograms, except when used in parenteral nutrition replacement preparations. Products containing 25 micrograms or less per day or for parenteral nutrition replacement are for general sale. Ergosterol in medicines containing more than 25 micrograms per recommended daily dose requires a prescription but available for general sale otherwise.
- The US Food and Drug Administration's Orange Book lists 6 products containing colecalciferol as one of the active ingredients as prescription only medicines. It also lists 5 ergocalciferol products as prescription only medicines.
- Ireland's Health Products Regulatory Authority regulates more than 50 products containing vitamin D3, colecalciferol or cholecalciferol or ergocalciferol. Among them 6 products are registered with the European Medicines Agency (EMA).

- The UK Electronic Medicines Compendium lists 41 products containing colecalciferol or cholecalciferol, comprising of 27 prescription-only medicines, 13 pharmacy-only medicines, and one general sale product. Additionally, there are 3 ergocalciferol medicines one of which is a prescription medicine, two are available from pharmacy and none is available for general sale.

1.2 Isotretinoin

Proposal

The applicant has proposed to amend the Appendix D, clause 2 entry for isotretinoin in the current Poisons Standard to extend prescribing rights to allow medical practitioners with advanced qualifications in general practice from the Australian College of General Practitioners (FRACGP) or the Australian College of Rural and Remote Medicine (FACRRM). Currently, only a specialist physician or a dermatologist can supply or prescribe isotretinoin for human use. If implemented, such specialist General Practitioners (GPs) will be allowed to prescribe isotretinoin under the same safety protocols currently applied to dermatologists.

CAS number

4759-48-2

Alternative names

13-*cis*-Retinoic acid, Roaccutane, Oratane, Dermatane

Applicant

Private applicant

Current Scheduling

Isotretinoin is currently included in Schedule 4 of the Poisons Standard and is subject to Appendix D restrictions. Isotretinoin also requires several warning statements under Appendix F and Appendix L.

Schedule 4

ISOTRETINOIN.

Index

ISOTRETINOIN

Schedule 4

Appendix D, clause 2

Appendix F, clause 4

Appendix L, clause 2

The current Appendix D, clause 2 entry limits prescribing oral isotretinoin medicines to a specialist physician or a dermatologist. If the patient is a woman of child-bearing age, the prescribing doctor must also advise the patient to avoid becoming pregnant during or for a period of 1 month after completion of treatment.

Under Appendix F, clause 4 (Poisons that must be labelled with warning statements and safety directions) and Appendix L, clause 2 (Additional warning statements for certain human medicines), isotretinoin preparations must be labelled with the below warning statements.

ISOTRETINOIN—for oral use

WARNING – Causes birth defects.

Do not use if pregnant.

Do not become pregnant during use or within (Insert number of months as per approved Product Information) month(s) of stopping treatment.

ISOTRETINOIN—for topical use

Do not use if pregnant.

WARNING – May cause birth defects.

Proposed Scheduling

The applicant has proposed amendments to the Appendix D, clause 2 entry for isotretinoin as follows.[2]

Item	Poison
4	ISOTRETINOIN for human oral use **except:** a) when used orally for the treatment of acne; and b) prescribed by a medical practitioner registered as a specialist in dermatology or a medical practitioner with advanced qualifications in general practice (Fellowship of the RACGP or ACRRM).

The Schedule 4 entry, and Appendix F and Appendix L warning statements remain unaltered.

Background

Isotretinoin (13-*cis*-Retinoic acid) is a retinoid compound, and a derivative of vitamin A. It is used as systemic retinoid for the treatment of severe cystic acne and other follicular skin conditions. Isotretinoin is highly effective but associated with significant risks, including teratogenicity, psychiatric effects, and liver toxicity. These risks are currently managed through prescriber restrictions, patient consent, and monitoring protocols.

Summary of applicant's reasons for the proposal

Currently, only medical practitioners registered as specialists in dermatology can prescribe oral isotretinoin. This change would amend the current prescriber limitation in Appendix D, Item 4 to include GPs with appropriate qualifications without affecting its Schedule 4 classification.

GPs are highly experienced in managing acne and are often the first point of care for these patients. Many already initiate and manage moderate to severe acne, including prescribing antibiotics and hormonal treatments. Allowing trained GPs to prescribe isotretinoin represents a safe and logical extension of existing care. The proposal recognises the capability of specialist GPs and supports collaborative care models between GPs and dermatologists where needed.

This proposal reflects a patient-centred update to prescribing regulations, improving access without compromising safety. The proposed changes would:

- increase timely access to effective acne treatment, especially for patients outside major metropolitan centres
- reduce avoidable scarring, physical discomfort, and long-term psychological harm

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

- align with modern models of care, recognising the role of well-trained GPs in managing complex, chronic skin conditions
- maintain patient safety by ensuring only GPs who complete specific accredited training are eligible to prescribe.

Key uses

- Used in medicines to treat severe cystic acne (primary indication)
- Off-label use is known for other conditions including rosacea, seborrhoea, hidradenitis suppurativa and discoid lupus erythematosus.

Australian regulations

- According to the TGA Ingredient Database, isotretinoin is available for use as:
  - an Active Ingredient in: Biologicals, Export Only, Prescription Medicines
  - an Excipient Ingredient in: Biologicals, Devices, Prescription Medicines.
- As of 12 September 2025, there were 37 medicines currently active on the Australian Register of Therapeutic Goods (ARTG) that contain isotretinoin as an active ingredient. These include 37 prescription medicines.
- Isotretinoin is not permitted to be included in listed medicines as it is not included in the Therapeutic Goods (Permissible Ingredients) Determination No. 2 of 2025.
- The TGA prescribing medicines in pregnancy database classifies isotretinoin as category X.

Drug name	Category	Classification Level 1	Classification Level 2	Classification Level 3
Isotretinoin (oral)	X	Drugs used in Dermatology	Systemic	
Category X – Drugs which have such a high risk of causing permanent damage to the foetus that they should not be used in pregnancy or when there is a possibility of pregnancy.				

- There are no warning statements for isotretinoin in the Therapeutic Goods (Medicines Advisory Statements) Specification 2021.
- As of 12 September 2025, there were 978 reports of adverse events for products containing isotretinoin as an active ingredient on the Database of Adverse Event Notifications (DAEN), with 896 reports where isotretinoin was the single suspected medicine. There were 31 reports of deaths associated with isotretinoin use.
- As of 12 September 2025, there were no products containing isotretinoin as an active ingredient/constituent or scheduled substance listed on the Public Chemical Registration Information System Search (PubCRIS).
- As of September 2025, isotretinoin was not listed on the Australian Inventory of Industrial Chemicals.

International regulations

- In Canada isotretinoin may be prescribed by non-dermatologist physicians under defined frameworks. Canada's National Drug Schedules Database classes isotretinoin as Schedule I (prescription only). The Health Canada Drug Product Database includes 14 entries, all of which are prescription medications. While general practitioners may prescribe it, the Canadian

Dermatology Association recommends referral to specialists if the prescriber is unfamiliar with its risks and management.

- In Europe the European Medicines Agency (EMA) and national regulatory bodies oversee isotretinoin use. Isotretinoin (oral formulations) medicinal products are listed on the EMA website.[3] A European Directive was introduced to harmonise prescribing practices across member states, particularly focusing on teratogenic risks and pregnancy prevention measures. While national practices may vary slightly, most of the EU members states follow similar restrictions, requiring specialist oversight and adherence to the Pregnancy Prevention Programme (PPP). Some countries allow prescribing by general practitioners with specific training or under specialist supervision.[4] The European prescribing directives on oral isotretinoin prescribing are summarised in the table below.[5]

Category	Directive Requirements
Indication	Severe acne (nodular/conglobata) unresponsive to standard therapy; not for <12 years old.
Dosage	Start at 0.5 mg/kg/day; titrate based on tolerance. No recognition of low-dose regimens.
Monitoring	Fasting lipids and live function tests: before treatment, at 1 month, then every 3 months.
Physical Treatments	Avoid chemical peels, laser therapy, wax depilation during and for 6 months post-treatment.
Pregnancy Prevention	Mandatory for females of childbearing potential: education, consent, supervised testing.
Pregnancy Testing	Before treatment, monthly during, and 5 weeks post-treatment.
Contraception	Two methods recommended; start treatment on day 3 of menstrual cycle.
Prescription Limits	Maximum 30-day supply; prescription valid for 7 days only.
Male Patients	PPP and prescription limits do not apply.
Implementation Challenges	Increased clinical burden, ethical concerns, financial costs, and continuity of care issues.

- The European Chemicals Agency (ECHA), based on information provided by companies under the *Classification, Labelling and Packaging Regulation*, considers isotretinoin may damage the unborn child; is very toxic to aquatic life with long lasting effects; causes serious eye irritation and skin irritation; and may cause respiratory irritation.
- The European Commission database for information on cosmetic substances and ingredients database lists isotretinoin as an anti-sebum ingredient under cosmetics regulation provisions II/375 (CosIng - Cosmetics - GROWTH - European Commission).
- In the UK, isotretinoin must be prescribed by a consultant dermatologist-led team and dispensed through hospital pharmacies.[6] The United Kingdom Electronic Medicines Compendium lists 9 prescription-only medicines containing isotretinoin.

[3] Isotretinoin (oral formulations): List of nationally authorised medicinal products - PSUSA-00010488-202405; accessed 12 September 2025

[3] Layton AM (2014). Prescribing Oral Isotretinoin: The European Approach. In: Zouboulis, C., Katsambas, A., Kligman, A. (eds) Pathogenesis and Treatment of Acne and Rosacea. Springer, Berlin, Heidelberg. DOI: 10.1007/978-3-540-69375-8_62

[5] Layton AM, Dreno B, Gollnick HP, Zouboulis CC (2006). A review of the European Directive for prescribing systemic isotretinoin for acne vulgaris. J Eur. Acad. Dermatol. Venereol. 20(7):773-6. DOI: 10.1111/j.1468-3083.2006.01671.x

[6] Isotretinoin for severe acne: who should prescribe it - GOV.UK

- Ireland's Health Products Regulatory Authority regulates 8 products containing isotretinoin. All are available for supply through pharmacies only and require prescription.
- The USA mandates prescriber registration and patient consent under the iPLEDGE program to minimize the risk of fetal exposure due to isotretinoin's high teratogenicity. Licensed healthcare providers including dermatologists, family physicians, and other qualified prescribers can prescribe isotretinoin, but only if they are registered and activated in the iPLEDGE Risk Evaluation and Mitigation Strategy program.
- The United States Food and Drug Administration's Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations includes 65 prescription-only containing isotretinoin medicines that are currently available. There are 7 records in the United States Food and Drug Administration Approved Drugs Database (Drugs@FDA) for isotretinoin.
- The New Zealand Medsafe Medicines Classification Database classifies isotretinoin as a prescription medication.

1.3 Mannitol

Proposal

The Department of Health, Disability and Ageing has proposed to create a new Pharmacist only medicine (Schedule 3) entry for mannitol for oral use for bowel cleansing in adults 18 years and over prior to diagnostic, medical or surgical procedures. Mannitol is currently unscheduled, but there are 4 registered therapeutic products for injection or inhalation.

CAS number

69-65-8

Alternative names

Manna sugar, mannite, D-mannitol, cordycepic acid

Proposed Scheduling

Mannitol is not specifically scheduled in the current Poisons Standard.

The applicant's proposed amendments to the Poisons Standard are[7]:

Schedule 3 – New Entry

MANNITOL in preparations for oral use for bowel cleansing (in adults 18 years and over) prior to diagnostic, medical or surgical procedures.

Index – New Entry

MANNITOL

Background

Mannitol is a sugar alcohol that has a long history of medical use for its diuretic and laxative properties, as an excipient in therapeutic preparations, and as a low-calorie sweetener in food. It is an osmotic diuretic. Once ingested, mannitol absorbs water from body tissues, particularly the gut lumen, and promotes bowel evacuation through rapid emptying of the colon.

[7] 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.

Summary of reasons for the proposal

Inclusion of mannitol in Schedule 3 will ensure safe access for use as a bowel cleansing agent prior to clinical procedures, such as endoscopy or radiology.

Many patients requiring bowel cleansing find options such as polyethylene glycol to be intolerable due to its unpleasant taste and high volume of intake required.

Mannitol is required to be ingested over a 30-minute period only 4 hours prior to the procedure, offering a shorter treatment time in comparison with other bowel cleansing agents. It also scored highly in ease of use, taste and adherence to course of treatment when trialled in a dose-finding clinical study, suggesting an improvement in patient experience whilst undergoing bowel preparation.

Mannitol does not present the risks of electrolyte abnormalities and renal disease usually associated and accepted the currently scheduled bowel cleansing agents, such as sodium phosphate and sodium picosulfate.

Associated risks of use include intestinal gas buildup, nausea, serum electrolyte changes and vomiting. There have been reported cases of colonic gas explosion, including one fatal incident, associated with its use as a bowel cleansing agent. Therefore, for the therapeutic use of mannitol in bowel cleansing, it is appropriate for risks to be managed through classification as a Pharmacist only medicine (Schedule 3), requiring professional advice from a pharmacist.

Key uses/expected use

The product, supplied as powder for ingestion with water, will be used as a bowel cleansing agent for preparation for clinical procedures requiring a clean bowel, such as endoscopy or x-ray examinations.

Australian regulations

- According to the TGA Ingredient Database, mannitol is:
  - available for use as an active ingredient in Biologicals, Export Only, Over the Counter and Prescription Medicines
  - available for use as an Excipient Ingredient in Biologicals, Devices, Export Only, Listed Medicines, Over the Counter, Prescription Medicines
  - not available as an Equivalent Ingredient in any application.
- As of 11 September, there were 10 medicines active on the Australian Register of Therapeutic Goods (ARTG) that contain mannitol as an active ingredient. All are non-prescription medicines, of which 4 are registered and 6 are listed (export only) medicines.
- According to the Therapeutic Goods (Permissible Ingredients) Determination No. 2 of 2025, mannitol is permitted to be included in listed medicines as follows.

Item	Ingredient name	Purpose	Specific requirements
3219	Mannitol	E	
E = excipient for a medicine meaning an ingredient that is not an active ingredient or a homoeopathic preparation ingredient			

- The TGA prescribing medicines in pregnancy database classifies mannitol as:

Drug name	Category	Classification Level 1	Classification Level 2	Classification Level 3
Mannitol	B2	Cardiovascular system		
Category B2 – Drugs which have been taken by only a limited number of pregnant women and women of childbearing age, without an increase in the frequency of malformation or other direct or indirect harmful effects on the human foetus having been observed. Studies in animals are inadequate or may be lacking, but available data show no evidence of an increased occurrence of foetal damage.				

- There are no warning statements pertaining to mannitol in the Therapeutic Goods (Medicines Advisory Statements) Specification 2021.
- As of 29 August 2025, there were 47 reports of adverse events for products containing mannitol as an active ingredient on the Database of Adverse Event Notifications (DAEN), with 26 reports where mannitol was the single suspected medicine. There were 2 reports of deaths associated with mannitol use.
- As of 12 September 2025, there were no products containing mannitol as an active ingredient/constituent or scheduled substance listed on the Public Chemical Registration Information System Search (PubCRIS).
- Mannitol is listed on the Australian Inventory of Industrial Chemicals.

International regulations

- According to the United States Food and Drug Administration Approved Drug Products Database (Drugs@FDA) and the The Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations, there is one product currently listed in the US for irrigation. The database also includes three listings of mannitol for inhalation and 14 listings for injection.
- The Health Canada Drug Product Database includes six listings of mannitol for injection but none for irrigation.
- The European Commission database for information on cosmetic substances and ingredients database contains one listing for mannitol.
- The European Chemicals Agency (ECHA) database search did not identify any hazard from mannitol based on the notifications provided by companies to ECHA.
- The New Zealand Medsafe Medicines Classification Database contains no listings for mannitol.

1.4 Efepoetin

Proposal

The Department of Health, Disability and Ageing has proposed creating Schedule 4 and Appendix D, clause 5 (Poisons for which possession without authority is illegal) entries for efepoetin alfa. The substance is not currently captured in the Poisons Standard.

CAS number

Efepoetin alfa: 1905452-78-9

Proposed Scheduling

The proposal is to create an entry for efepoetin alfa as follows:[8]

Schedule 4 – New entry

Efepoetin alfa

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

Item	Poison
11	Efepoetin alfa

Background

Efepoetin alfa is a long-acting recombinant form of human erythropoietin that acts as an erythropoiesis-stimulating agent intended to treat anaemia in patients with chronic kidney diseases. It is a fusion protein consisting of a homodimeric erythropoietin fused to a hybrid Fc domain derived from immunoglobulin D and G4.[9] The hybrid Fc domain binds to the Fc receptor but lacks complement activation ability leading to lower cytotoxicity and better safety. The hybrid Fc region also helps erythropoietin to remain in the body longer through Fc receptor recycling.

Summary of reasons for the proposal

Efepoetin alfa is a new chemical entity with limited experience of use of the substance under normal clinical conditions. Additionally, treatment of anaemia in chronic kidney disease patients requires medical diagnosis and on-going clinical management by a kidney specialist (nephrologist).

Efepoetin alfa shares a similar risk profile to other synthetic erythropoetins such as epoetins (alfa, beta, and lambda) and darbepoetin alfa that are already available for the same indication. The proposal would align the scheduling of efepoetin alfa, a recombinant form of human erythropoietin, with other erythropoetins.

Erythropoetins have historically been subject to misuse and abuse among certain communities, particularly athletes, and are banned by the World Anti-Doping Agency (WADA). Additional access restrictions would reduce the risk of misuse and abuse of efepoetin alfa and align the scheduling with that of other erythropoetins.

Key uses/expected use

Efepoetin alfa will be available in prefilled syringes for subcutaneous injection for the treatment of anaemia in chronic kidney disease patients.

Australian regulations

- According to the TGA Ingredient Database, efepoetin alfa is available for use as an active ingredient in Prescription Medicines. It is not available for use as an excipient or an equivalent ingredient in any application. Erythropoietin is available as an active or excipient ingredient in biologicals and prescription medicines. Epoetin and darbepoetin alfa are available as an active or excipient ingredient in biologicals, prescription and export-only medicines.

[8] 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.

[9] Roger et al., (2025) Non-Inferiority of Subcutaneous Efepoetin Alfa Compared to Methoxy Polyethylene Glycol-Epoetin Beta in Stage 3 or 4 CKD Patients: Insights From a Phase 3 Trial. Nephrology (Carlton). 30(5):e70046. DOI: 10.1111/nep.70046.

- As of 12 September 2025, there were no medicines currently active on the Australian Register of Therapeutic Goods (ARTG) that contain efepoetin alfa or erythropoietin as an active ingredient. There are 36 medicines currently active containing epoetins as an active ingredient.
- None of efepoetin alfa, erythropoietin or epoetins are permitted to be included in listed medicines as not included in the Therapeutic Goods (Permissible Ingredients) Determination No. 2 of 2025.
- The TGA prescribing medicines in pregnancy database does not include efepoetin alfa. Erythropoietin and epoetins are classified as:

Drug name	Category	Classification Level 1	Classification Level 2	Classification Level 3
Erythropoietin	B3	Blood and Haemopoietic System	Haemopoietic agents	-
Epoetin alfa	B3	Blood and Haemopoietic System	Haemopoietic agents	-
Epoetin beta (rch)	B3	Blood and Haemopoietic System	Haemopoietic agents	-
Epoetin lambda (rch)	B3	Blood and Haemopoietic System	Haemopoietic agents	-
Category B3 – Drugs which have been taken by only a limited number of pregnant women and women of childbearing age, without an increase in the frequency of malformation or other direct or indirect harmful effects on the human foetus having been observed. Studies in animals have shown evidence of an increased occurrence of foetal damage, the significance of which is considered uncertain in humans.				

- There are no warning statements pertaining to erythropoietin or epoetins in the Therapeutic Goods (Medicines Advisory Statements) Specification 2021.
- As of 12 September 2025, there were no reports of adverse events for products containing efepoetin alfa as an active ingredient on the Database of Adverse Event Notifications (DAEN). There were 2 reported cases of adverse events for products containing erythropoietin as an active ingredient. Both incidents involved exposure during pregnancy and erythropoietin was not the single suspected medicine. There were 358 reports of adverse events for products containing epoetins or darbepoetin alfa with 25 resulting in death. Epoetins or darbepoetin alfa were the single suspected medicine in 261 of these cases.
- In 2009-19 there were no adverse experiences recorded for efepoetin alfa, erythropoietin or epoetins in the APVMA Adverse Experience Reporting Program database (AERP).

International regulations

- The World Anti-Doping Agency lists erythropoietin receptor agonists, including darbepoetins, erythropoetins and epoetins as substances prohibited from use at all times.
- The United States Food and Drug Administration Approved Drug Products Database (Drugs@FDA) does not include efepoetin alfa or erythropoietin, though there are 3 prescription only medicines approved containing epoetins and 1 containing darbepoetin alfa.
- The European Commission does not include efepoetin alfa or erythropoietin, but lists epoetins as an active ingredient in 12 prescription only medicines and darbepoetin alfa as an active ingredient in 2 prescription only medicines.

- In New Zealand, erythropoietin, epoetins and darbepoetin are classified as prescription medicines in the New Zealand Medicines and Medical Devices Safety Authority (MedSafe).
- The Canadian (Health Canada) Drug Product Database lists 6 prescription medicines and 6 Schedule D medicines (biologic drugs which require specific regulatory oversight and market authorization from Health Canada before they can be sold) containing darbepoetin. Efepoetin alfa, erythropoietin, or epoetins are not listed in the database.
- Currently, efepoetin alfa is approved in Indonesia for treating anaemia in non-dialysis chronic kidney disease (CKD) patients. A multinational Phase III clinical trial targeting dialysis patients in currently under progress.[10, 11, 12]

2 Proposed amendments referred for scheduling advice to ACCS meeting #41

2.1 Oxalic acid

Proposal

The proposal is to amend the current Poison Standard with regards to the Poison (Schedule 6) entry 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 will be unscheduled and will be available without the POISON signal heading or any first aid instructions, warning statements and general safety directions currently applicable to them.

CAS Number

144-62-7

Alternative names

Ethanedioic acid

Applicant

Private applicant

Proposed Scheduling

Oxalic acid is currently listed in Schedule 6 of the Poisons Standard as follows:

Schedule 6

OXALIC ACID **except**

(a) in dental care preparations, including mouthwashes, containing 3% or less of soluble salts of oxalic acid; or

[10] Genexine (2023) Genexine and KGbio received the first market approval for novel long-acting Erythropoietin, Efepoetin alfa, from The Indonesian Food and Drug Authority (BPOM); accessed 15 September 2025.

[11] NIH (2024) A Phase 3 Study of Efepoetin Alfa for Treatment of Anemia in Patients With Chronic Kidney Disease on Dialysis; accessed 15 September 2025.

[12] European Clinical Trials (n.d.) Study on Efepoetin Alfa and Darbepoetin Alfa for Treating Anemia in Patients with Chronic Kidney Disease on Dialysis; accessed 15 September 2025.

(b) its insoluble salts.

It is also included under the entry OXALIC ACID in Appendix E and Appendix F as follows:

Appendix E, Clause 2 – First aid instructions for poisons

For advice, contact a Poisons Information Centre (e.g. phone Australia 13 11 26; New Zealand 0800 764 766) or a doctor (at once).

If swallowed, do NOT induce vomiting.

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.

If skin or hair contact occurs, remove contaminated clothing and flush skin and hair with running water.

Appendix F, Clause 3 – Warning statements and general safety directions for poisons

Corrosive.

Avoid contact with skin.

Avoid breathing dust (or) vapour (or) spray mist.

The applicant's proposed amendments to the Poisons Standard are[13]:

Schedule 6 –Amend Entry

OXALIC ACID **except:**

(a) in dental care preparations, including mouthwashes, containing 3% or less of soluble salts of oxalic acid; or

(b) its insoluble salts; or

(c) in commercial, household or domestic cleaning products, containing 9.5% or less of soluble salts of oxalic acid.

Background

Oxalic acid is used for removing rust, tarnish, mineral deposits and tough stains from variety of surfaces including wood surface, concrete, stainless steel, glass and porcelain in industrial, domestic and household applications. It is an ingredient in bathroom and toilet cleaners, metal polish and descaler, etching agent in metal finishing and is a laboratory reagent.

Summary of applicant's reasons for the proposal

While oxalic acid is corrosive at higher concentrations, the proposed amendment applies only to products with 9.5% or less oxalic acid – levels that are considered manageable with proper labelling and packaging. Oxalic acid at concentrations up to 9.5% is permitted in household cleaning products in the USA, Canada, UK, and EU.

These products are intended to be used for low-exposure, routine cleaning applications. Products such as Bar Keepers Friend have a long history of safe use and are certified by National Sanitation Foundation as meeting the public health and safety standards for use in domestic, commercial, and industrial kitchens.

Product formats include robust sealed containers, spray bottles, and sealed powders, each labelled with explicit safety instructions. These presentations are consistent with international standards and appropriate for household use.

[13] 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.

There is minimal risk of abuse or misuse, and risk can be further reduced through robust packaging including child-resistant features where applicable, and prominent warning and safety labels.

In Australia, oxalic acid containing cleaning products are classified as Poison (Schedule 6). Therefore, international manufacturers need to adjust the formula to contain citric acid to maintain Australian standards. This amendment would harmonise Australia's regulations with international markets, ensuring consistent global formulations, streamlined supply chains, and reduced regulatory burden for international manufacturers without compromising health outcomes.

Key and expected use

In Australia, oxalic acid is mostly found as dry powder (Diggers Rust & Stain Cleaner) for use on kitchen appliances, plumbing fixtures, cement surfaces, timbers and masonry or as 10% solution (deck cleaners). The applicant intends to market commercial, household and domestic cleaning products containing 9.5% or less oxalic acid.

Australian regulations

- According to the TGA Ingredient Database, oxalic acid is:
  - available for use as an active ingredient in: Biologicals, Export Only, Listed Medicines, Over the Counter, and Prescription Medicines.
  - available for use in Listed Medicines as a Homoeopathic Ingredient only up to a total concentration of 10 mg/kg or 10 mg/L or 0.001%.
  - available for use as an Excipient Ingredient in: Biologicals, Devices, Prescription Medicines
  - not available as an Equivalent Ingredient in any application.
- As of 15 September 2025, there were no medicines currently active on the Australian Register of Therapeutic Goods (ARTG) that contain oxalic acid as an active ingredient.
- According to the Therapeutic Goods (Permissible Ingredients) Determination No. 2 of 2025, oxalic acid is permitted to be included in listed medicines as follows.

Item	Ingredient name	Purpose	Specific requirements
3633	Oxalic acid	H	Only for use as an active homoeopathic ingredient. The total concentration of oxalic acid in the medicine must not be more than 10 mg/kg or 10 mg/L or 0.001%.
H = homoeopathic preparation ingredient meaning an ingredient that is a constituent of a homoeopathic preparation			

- The TGA prescribing medicines in pregnancy database does not include oxalic acid.
- There are no warning statements pertaining to oxalic acid in the Therapeutic Goods (Medicines Advisory Statements) Specification 2021.
- As of 15 September 2025, there were no reports of adverse events for products containing oxalic acid as an active ingredient on the Database of Adverse Event Notifications (DAEN).
- As of 15 September 2025, there were no products containing oxalic acid as an active ingredient/constituent or scheduled substance listed on the Public Chemical Registration Information System Search (PubCRIS).
- In 2009-2019, no adverse experiences were recorded for oxalic acid in the APVMA Adverse Experience Reporting Program database.

- Oxalic acid is listed on the Australian Inventory of Industrial Chemicals and a Human Health Tier II Assessment of Oxalic acid was published by the National Industrial Chemicals Notification and Assessment Scheme (now Australian Industrial Chemicals Introduction Scheme) in 2014.

International regulations

- In the United States Environmental Protection Agency's Office of Pesticide Programs Database oxalic acid is registered, and its pesticide type is listed as conventional chemical pesticide.
- In Europe, oxalic acid is listed in European Commission database for information on cosmetic substances and ingredients database (CosIng) as a chelating substance.
- According to European Chemical Agency (ECHA), oxalic acid is registered under the REACH (Registration, Evaluation, Authorisation, and Restriction of Chemicals) Regulation and is manufactured in and/or imported to the European Economic Area. The substance has widespread use including consumer products for coating, polishes, waxes, washing and cleaning. According to the harmonised classification and labelling (CLP00) approved by the European Union, this substance is harmful if swallowed and is harmful in contact with skin. Oxalic acid is also identified as a substance that can cause serious eye damage.
- In the EU and ASEAN countries and New Zealand, the use of oxalic acid in hair products is restricted to professional use and at a maximum concentration of 5% through listing in the following:
  - ASEAN Cosmetic Directive Annex III – Part 1 (List of substances which cosmetic products must not contain except subject to restrictions and conditions laid down)
  - EU Regulation (EC) No 1223/2009 Annex III (List of substances which cosmetic products must not contain except subject to the restrictions laid down).
- In New Zealand, oxalic acid is not individually approved but may be used under an appropriate group standard with similar GHS classification and toxicity data (New Zealand Inventory of Chemicals (NZIoC) database). New Zealand has also placed restrictions on oxalic acid in hair care products similar to EU and the ASEAN countries by placing it in the New Zealand Cosmetic Products Group Standard (Schedule 5—Table 1; Components cosmetic products must not contain except subject to the restrictions and conditions laid down).
- As of 28 August 2025, oxalic acid is not listed in European Commission Comitology Register, New Zealand Medicines and Medical Devices Safety Authority (MedSafe), The Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations, and United States Food and Drug Administration Approved Drug Products Database (Drugs@FDA). In the Health Canada Drug Product Database, oxalic acid is listed in 7 cancelled post-market homeopathic products.

3 Proposed amendments referred for scheduling advice to the Joint ACMS-ACCS meeting #42

3.1 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 Schedule 4 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.

CAS Number

123-31-9

Alternative names

1,4-Benzoquinol; p-dihydroxybenzene; hydroquinol; quinol

Proposed Scheduling

Hydroquinone is currently listed in Schedules 2, 4 and 6 of the Poisons Standard as follows:

Schedule 2

HYDROQUINONE (excluding monobenzone and alkyl ethers of hydroquinone included in Schedule 4) in preparations for human external therapeutic or cosmetic use 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

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

(a) when included in Schedule 2; or

(b) in hair preparations containing 0.3% or less of hydroquinone; or

(c) in cosmetic nail preparations containing 0.02% or less of hydroquinone.

Schedule 6

HYDROQUINONE **except**:

(a) when included in Schedule 2 or 4; or

(b) in preparations containing 10% or less of hydroquinone.

It is also included under the entries HYDROQUINONE in Appendix E and F as follows:

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

All scheduled hydroquinone preparations must be labelled with the statement:

For advice, contact a Poisons Information Centre (e.g. phone Australia 13 11 26; New Zealand 0800 764 766) or a doctor (at once).

All Schedule 4 and Schedule 6 preparations are to be additionally labelled with the following statements.

If swallowed, give activated charcoal if instructed.

If swallowed, do NOT induce vomiting.

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.

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.

If skin or hair contact occurs, remove contaminated clothing and flush skin and hair with running water.

Appendix F, Clause 4 – Warning statements and general safety directions for poisons

Schedule 2 preparations of hydroquinone must be labelled with the statements:

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.

All hydroquinone preparations except ones included in Schedules 2 and 4, must be labelled with the following statements:

Avoid contact with eyes

Avoid contact with eyes.

The proposed amendments to the Poisons Standard are[14]:

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 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**:

~~(a) when included in Schedule 2; or~~

(b) in hair preparations containing 0.3% or less of hydroquinone; or

(c) in cosmetic nail preparations containing 0.02% or less of hydroquinone.

Schedule 6 – Amend entry

HYDROQUINONE **except**:

(a) when included or expressly excluded from ~~in~~ Schedule ~~2 or~~ 4; or

(b) in preparations containing 10% or less of hydroquinone.

Appendix E, clause 3 and Appendix F, clause 4 will be amended to remove the references to Schedule 2 preparations. First aid instructions, warning statements and safety directions applicable to other schedule preparations will remain the same.

Appendix E, Clause 3 – Amend entry

Poisons that must be labelled with first aid instructions		
Item	**Column 1** **Poison**	**Column 2** **Statement code**
~~152~~	~~HYDROQUINONE—when included in Schedule 2~~	~~A~~
153	HYDROQUINONE—when included in Schedule 4 or 6	A, G2, G3, E2, R2, S1

[14] 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 – Amend entry

Poisons that must be labelled with warning statements and safety directions			
Item	**Column 1** **Poison**	**Column 2** **Warning statement item number**	**Column 3** **Safety direction item number**
~~176~~	~~HYDROQUINONE—when included in Schedule 2~~	~~45~~	
177	HYDROQUINONE—except when included in Schedule ~~2 or~~ 4		1, 4

Background

Hydroquinone is a skin lightening agent that acts by inhibiting melanin production. It can be used to treat skin and nail hyperpigmentation or discoloration. It is also used as a photographic developer, antioxidant, stabiliser (in paints, fuels, oils and polymers), chemical intermediate and in pharmaceuticals.

The current exemptions in the Poisons Standard allow hydroquinone to be used in hair preparations at up to 0.3% and cosmetic nail preparations at up to 0.02%. In hair preparations hydroquinone is used as a coupler agent to induce or enhance chemical processes which lead to the formation of oxidative hair dyes. Hydroquinone is used in cosmetic nail preparations to inhibit the polymerisation of certain monomers.

In February 2009, the National Drugs and Poisons Schedule Committee (NDPSC) deferred the up scheduling of hydroquinone for human external use (excluding hair dyes) from Schedule 2 to Schedule 3 pending the US Food and Drug Administration (FDA) review of hydroquinone. In September 2020, the Coronavirus Aid, Relief, and Economic Security Act (CARES Act) banned the sale of over-the-counter hydroquinone in the USA unless approved by the FDA.[15] The FDA also advised consumers not to use these products due to the potential harm including permanent discoloration of skin (ochronosis) these products may cause.

Summary of the reasons for the proposal

Hydroquinone is used in hair, cosmetic nail and skin lightening preparations. Hydroquinone was first included in Schedule 4 of the Poisons Standard in 1969 due to concerns regarding promotion and availability of skin lightening creams targeted to Papua New Guinean and Indigenous Australian populations.

Dermal use of 2-4% hydroquinone has been associated with side effects including rashes, facial swelling, and permanent skin discoloration. Topical hydroquinone may also cause transient erythema, mild burning sensation and occasional hypersensitivity. Higher concentrations preparations are more likely to be irritants and have a greater risk of ochronosis. Animal studies have also reported carcinogenicity including hepatic adenomas, renal adenomas, and leukemia from extended exposure to large doses of oral hydroquinone.[16]

Internationally, the EU has banned hydroquinone use in cosmetic preparations for skin lightening, though it is still available as a prescription medicine. Similarly, the US FDA effectively banned the sale of over-the-counter hydroquinone products for skin lightening in September 2020. This proposal would align Australian regulations with the EU and US for skin lightening preparations.

[15] FDA (2022) FDA works to protect consumers from potentially harmful OTC skin lightening products

[16] Levitt (2007) The safety of hydroquinone: A dermatologist's response to the 2006 *Federal Register*. Volume 57, Issue 5, 854 - 872

Key uses / expected use

Medicines, cosmetic, industrial use.

Australian regulations

- According to the TGA Ingredient Database, hydroquinone is:
  - Available for use as an active ingredient in Biologicals, Export Only, Over the Counter and Prescription Medicines.
  - Available for use as an Excipient Ingredient in Biologicals, Devices, Export Only, Over the Counter, and Prescription Medicines.
  - Available for use as an Equivalent Ingredient in Listed Medicines.
- As of 11 September 2025, there were 6 medicines currently active on the Australian Register of Therapeutic Goods (ARTG) that contain hydroquinone as an active ingredient. These include 3 export-only medicines and 3 non-prescription medicines.
- According to the Therapeutic Goods (Permissible Ingredients) Determination No. 2 of 2025, hydroquinone is a mandatory component in the following ingredients which can only be used in dermal face products when the concentration of hydroquinone in dermal products does not exceed 10 mg/kg or 10 mg/L or 0.001%.
  - ACHILLEA MILLEFOLIUM
  - ARCTOSTAPHYLOS UVA-URSI
  - CHIMAPHILA UMBELLATA
  - KALMIA LATIFOLIA
  - LEDUM PALUSTRE
  - ORIGANUM MAJORANA
  - PYRUS COMMUNIS
  - PYRUS PYRIFOLIA
  - RHODODENDRON FERRUGINEUM
  - TURNERA DIFFUSA
  - VACCINIUM VITIS-IDAEA
- The TGA prescribing medicines in pregnancy database does not include hydroquinone.
- The Therapeutic Goods (Medicines Advisory Statements) Specification 2021 requires the following warning statements pertaining to hydroquinone to be included on the labelling.

Substance	Conditions	Required statements
Hydroquinone	In Schedule 2 to the current Poisons Standard	• 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.

Substance	Conditions	Required statements
		• Mild irritation may occur; stop use if it becomes severe. • If fading is not evident in 3 months, seek doctor's advice. • Do not exceed recommended dose. Excessive or prolonged use should be avoided because darkening of the skin can occur.

- The Specification would need to be amended should the scheduling proposal be implemented as the entry would no longer be applicable.
- As of 12 September 2025, there were 3 reports of adverse events for products containing hydroquinone as an active ingredient on the Database of Adverse Event Notifications (DAEN), with 1 report where hydroquinone was the single suspected medicine. There were no reports of deaths associated with hydroquinone use.
- As of 12 September 2025, there were no products containing hydroquinone as an active ingredient/constituent or scheduled substance listed on the Public Chemical Registration Information System Search (PubCRIS).
- In 2009-2019, no adverse experiences were recorded for hydroquinone in the APVMA Adverse Experience Reporting Program database.
- Hydroquinone is listed on the Australian Inventory of Industrial Chemicals with an evaluation statement published in December 2022 noting potential environmental hazards.

International regulations

- In the United States (US), the Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations and Drugs@FDA: FDA-Approved Drugs include 1 approved prescription only topical preparation (product name: TRI-LUMA) containing 4% hydroquinone. No OTC skin lightening products containing hydroquinone can be marketed unless approved by the FDA.
- According to European Chemical Agency (ECHA), hydroquinone is very toxic to aquatic life; causes serious eye damage; is harmful if swallowed; is suspected of causing genetic defects and cancer; and may cause an allergic skin reaction.
- Under the Cosmetic Products Regulation, Annex II (Prohibited Substances) Hydroquinone in cosmetic products is not permitted in the EU except for use as an oxidising colouring agent in hair dyes at up to 0.3%.
- Hydroquinone is listed in European Commission database for information on cosmetic substances and ingredients database (CosIng) with functions including antioxidant, bleaching, hair dyeing, fragrance, and reducing.
- In New Zealand Inventory of Chemicals (NZIoC) database, hydroquinone is listed as approved with controls.

- The New Zealand Medsafe Medicines Classification Database listed hydroquinone as follows.

Substance	Conditions (if any)	Classifications
Hydroquinone	**except** in medicines for external use containing 2% or less	Prescription
Hydroquinone	for external use in medicines containing 2% or less except in hair preparations containing 1% or less	Pharmacy Only
Hydroquinone	for external use in hair preparations containing 1% or less	General Sale

- As of 12 September 2025, the Health Canada Drug Product Database listed hydroquinone in relation to 67 cancelled drug products and 1 marketed prescription product for human.

How to respond

Submissions must be provided by the closing date of 17 October 2025 through our consultation hub. Any submission about any of the proposals to amend the Poisons Standard will be considered at the next meeting of the Advisory Committee on Medicines Scheduling (ACMS), meeting of the Advisory Committee on Chemicals Scheduling (ACCS), or a joint meeting of these two committees.

What will happen

All public submissions will be published on the TGA website at Public submissions on scheduling matters, unless marked confidential or indicated otherwise in the submission coversheet (see Privacy information).

Following consideration of public submissions received before the closing date and advice from the expert advisory committee/s, decisions on the proposed amendments will be published as interim decisions on the TGA website Scheduling decisions (interim) in February 2026.

Therapeutic Goods Administration

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