Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Consultation: Proposed amendments to the Poisons Standard – ACMS #46 and Joint ACMS-ACCS #38 meetings, November 2024

23 September 2024

Version 1.0

Confidentiality

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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 2024** meetings of the Advisory Committee on Medicines Scheduling (ACMS), and Advisory Committee on Medicines and Chemicals Scheduling in joint session (Joint ACMS-ACCS). Submissions must be received by close of business 22 October 2024.

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 22 October 2024.

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

Proposed amendment referred for scheduling advice to ACMS meeting #46

Astodrimer sodium

Proposal

The applicant proposed an amendment to the entries relating to astodrimer sodium. The proposed amendment would include astodrimer sodium as Pharmacy medicine (Schedule 2) when used as a vaginal gel for treatment, relief and prevention of bacterial vaginosis. These preparations are currently a Pharmacist Only medicine (Schedule 3). The proposed amendment to the Appendix H entry would permit advertising of all Schedule 3 preparations of astodrimer sodium. The current Appendix H entry only allows advertising of preparations for the treatment and relief of bacterial vaginosis and prevention of recurrent bacterial vaginosis.

Astodrimer sodium is currently approved for use as an active ingredient in medical devices.

CAS number

676271-69-5

Alternative names

2, 6-Bis-{(1-napthalenyl-3,6-disulfonic acid)-oxyacetamido}-2,6-bis-2,6-bis-2,6-bis-(2,6-diamino-hexanoylamino)-2,6-diamino-hexanoic acid (diphenylmethyl)-amide, polysodium salt; SPL7013

Applicant

Private applicant

Proposed Scheduling

Astodrimer sodium is currently listed in Schedule 2, Schedule 3, Appendix F and Appendix H of the Poisons Standard.

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

Schedule 2 – Amend Entry

ASTODRIMER SODIUM when used in:

(a) nasal spray; or

(b) a vaginal gel for the treatment and relief of bacterial vaginosis and for the prevention of recurrent bacterial vaginosis.

[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.

Schedule 3

ASTODRIMER SODIUM **except**:

(a) when included in Schedule 2; or

(b) in a condom lubricant.

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ASTODRIMER SODIUM

Schedule 2
Schedule 3
Appendix F, clause 4
Appendix H, clause 1

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

Item	Poison	Warning statement
30	ASTODRIMER SODIUM – for the treatment and relief of bacterial vaginosis	**63** – See a doctor (or) (dentist) if no better after (Insert number of days as approved Product Information) days.
		64 – If getting better, keep using for (Insert number of days as per approved Product Information) days.
		69 – If symptoms recur within two weeks of completing the course, consult a doctor.
		75 – Do not use under waterproof bandages unless a doctor has told you to.
		109 – See your healthcare provider is you consider that you may be at risk of a Sexually Transmitted Infection (STI).
		110 – See a doctor if you plan to become pregnant or are breastfeeding or plan to breastfeed.
31	ASTODRIMER SODIUM – for the prevention of recurrent bacterial vaginosis	**63** – See a doctor (or) (dentist) if no better after (Insert number of days as approved Product Information) days.
		75 – Do not sue under waterproof bandages unless a doctor has told you to.
		109 – See your healthcare provider is you consider that you may be at risk of a Sexually Transmitted Infection (STI).
		110 – See a doctor if you plan to become pregnant or are breastfeeding or plan to breastfeed.

Appendix H, clause 1 – Schedule 3 medicines permitted to be advertised.

Item	Poison
3	ASTODRIMER SODIUM ~~– for the treatment and relief of bacterial vaginosis and for the prevention of recurrent bacterial vaginosis~~

Background

Astodrimer sodium is a low toxicity, non-antibiotic, microbicidal that is used in several medical devices including a vaginal gel for the treatment of bacterial vaginosis (BV) and prevention of recurrent bacterial vaginosis (RBV), condom lubricant for the prevention of sexually transmitted infections (STI), and in a nasal spray to trap and block respiratory viruses.

Astodrimer sodium is currently included in Schedule 3, except when used in a nasal spray (Schedule 2) or used in a condom lubricant (unscheduled). In preparations for the treatment and relief of BV or prevention of RBV, astodrimer sodium also requires warning statements and general safety directions through inclusion in Appendix F. The Appendix H entry for astodrimer sodium permits advertising for preparations used in the treatment and relief of bacterial vaginosis and for the prevention of recurrent bacterial vaginosis.

Summary of applicant's reasons for the proposal

- The final decision regarding astodrimer sodium for use as a nasal spray, published in May 2024, highlighted the importance of access to health professional advice at the point-of-sale for products containing astodrimer sodium to mitigate risks of misdiagnosis and inappropriate use.
- The availability of self-testing medical devices (IVDs) to aid diagnosis of vaginal symptoms, along with access to health professionals at the point of sale, supports consumer accuracy in self-diagnosing and selecting appropriate treatment options for BV and RBV.
- Preparations of astodrimer sodium for the treatment of BV and prevention of RBV have been available since 2019, providing over 5 years of post-market data.
- Astodrimer sodium poses low risk of harm, as noted in the delegate's previous decisions published in November 2021 and May 2024. The risks associated with misuse, abuse and overuse are very low. Astodrimer sodium is not systemically absorbed when used as a nasal spray.
- Adverse effects are rare and well-characterised, with no known interactions with commonly used food and consumables, or contra-indications. The risk profile of the substance is well defined, and risks can be appropriately managed through labelling and packaging.

Key uses/expected use

Used in medical devices.

Australian regulations

- According to the TGA Ingredient Database, astodrimer sodium is:
  - Available for use as an Active Ingredient in: Devices
  - Available for use as an Excipient Ingredient in: Devices
  - Not available as an Equivalent Ingredient in any application
- As of 22 August 2024, there were no medicines currently active on the Australian Register of Therapeutic Goods (ARTG) that contain astodrimer sodium as an active ingredient. One medical device containing astodrimer sodium as a vaginal flora gel is registered on the ARTG (ARTG entry 295465).
- Astodrimer sodium is not permitted to be included in listed medicines as it is not included in the Therapeutic Goods (Permissible Ingredients) Determination No.2 of 2024.

- Astodrimer sodium is not listed in the TGA prescribing medicines in pregnancy database.
- There are no warning statements pertaining to astodrimer sodium in the Therapeutic Goods (Medicines Advisory Statements) Specification 2021.
- As of August 2024, there were no reports of adverse events for products containing astodrimer sodium as an active ingredient on the Database of Adverse Event Notifications (DAEN).
- As of 22 August 2024, there were no products containing astodrimer sodium as an active ingredient/constituent or scheduled substance listed on the Public Chemical Registration Information System Search (PubCRIS).

International regulations

- Astodrimer sodium is not included in the Health Canada drug product database, the United States Food and Drug Administration's approved drug products database, the New Zealand Inventory of Chemicals, the New Zealand Medicines and Medical Devices Safety Authority (MedSafe), the European Commission database for information on cosmetic substances and ingredients or Ireland's Health Products Regulatory Authority medicines database.

Atropa belladonna

Proposal

The delegate of the Secretary of the Department of Health and Aged Care that is responsible for medicines scheduling (the Delegate)[2] is seeking advice from the Advisory Committee on Medicines Scheduling on a proposal to remove the Pharmacy medicine (Schedule 2) entry for *Atropa belladonna* from the Poisons Standard, making all preparations a Prescription Only medicine (Schedule 4).

CAS number

A combination of compounds including atropine (CAS No. 51-55-8) and hyoscine (CAS No. 101-31-5)

Alternative names

Belladonna, deadly nightshade, divale, dwale, banewort, devil's berries, great morel, and dwayberry.

[2] For the purposes of s 52D of the *Therapeutic Goods Act 1989* (Cth).

Proposed scheduling

Atropa belladonna is included in the Poisons standard in Schedule 4 and Schedule 2 and Appendix G. The proposed amendments to the Poisons Standard are:[3]

Schedule 4

ATROPA BELLADONNA (belladonna) **except** ~~when included in Schedule 2.~~

Schedule 2 –Delete Entry

~~ATROPA BELLADONNA (belladonna):~~

~~(a) for external use in preparations containing 0.03 per cent or less of total solanaceous alkaloids; or~~

~~(b) for oral use preparations included in the Register when:~~

~~(i) in undivided preparations containing 0.03 per cent or less of total solanaceous alkaloids when labelled with a dose of 0.3 mg or less of total solanaceous alkaloids and a recommended daily dose of 1.2 mg or less of total solanaceous alkaloids; or~~

~~(ii) in divided preparations containing 0.3 mg or less of total solanaceous alkaloids per dosage unit, when labelled with a recommended daily dose of 1.2 mg or less of total solanaceous alkaloids.~~

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ATROPA BELLADONNA
cross reference: BELLADONNA
Schedule 4
~~Schedule 2~~
Appendix G, clause 1

Appendix G
Atropa belladonnas exempt at or below certain concentrations
For the purposes of paragraph 11(c), the following table specifies:
(a) atropa belladonnas; and
(b) concentrations in relation to those atropa belladonnas.

Item	Column 1 Atropa belladonna	Column 2 Concentration (quantity per litre or kilogram)
6	ATROPA BELLADONNA (belladonna)	300 micrograms

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

Background

Atropa belladonna contains naturally occurring muscarinic receptor antagonists – alkaloids of the belladonna plants. The most important of these are atropine and hyoscine (scopolamine). Belladonna is a plant that contains compounds that produce anticholinergic[4] activity. Atropa belladonna has been scheduled since 1955 and its scheduling has been considered several times.

Atropa belladonna is used in topical preparations for muscle and joint pain and in dry cough formulations sold over the counter.

'Colic' is an out-dated term used to describe excessive crying and popular 'colic treatments' such as gripe water, herbal remedies and homeopathy are not indicated. Some 'colic preparations' contain belladonna which poses significant additional risks.

Summary of the reasons for the proposal

- Several adverse event reports have been received regarding *Atropa belladonna* products purchased by the members of the public.
- From the beginning of 2023, there have been 49 adverse events where *Atropa belladonna* was considered the main ingredient that caused the event. These can all assumed to be in children under 6. Over half (28 of the events) did not list the age of the infant but were using a 'colic' product intended for infants. Of the remaining 21 adverse events, 19 were in children under 1 year, and 2 were in 3-year olds.
- All adverse events from 2023 onwards are associated with a single product compounded by pharmacists. There are no products approved by the Therapeutic Goods Administration.
- There is little reliable information on safe paediatric doses for preparations containing belladonna tincture.
- The current Poisons Standard entry, when it was last considered in 2006, did not take children's dosages into account and the concentration cut-offs were based on harmonisation with New Zealand and not on considerations of paediatric doses.
- Signs of overdose with this medicine, for example lethargy, reduction in crying, resembles the signs of a toxic dose and could be easily confused by consumers. Belladonna toxicity can cause symptoms in an infant that include dry mouth and skin, dilated pupils, inability to pass urine, floppiness and poor feeding.
- Onset of toxicity is usually within 30 minutes to 4 hours; symptoms may be significantly delayed or prolonged due to decreased gastric motility and may vary due to frequent and repeated dosing.
- It should be noted that products that contain belladonna tincture are often compounded from leaves; the amount of alkaloids can vary greatly, depending on growing conditions and plant to plant variations.

Key uses/expected use

Medicines

[4] Anticholinergics are substances that block the action of the acetylcholine neurotransmitter at synapses in the central and peripheral nervous system.

Australian regulations

- According to the TGA Ingredient Database, *Atropa belladonna* is:
  - Available for use as an Active Ingredient in: Export Only, Listed Medicines, Over the Counter, Prescription Medicines
  - Also available for use as a Homoeopathic Ingredient in Listed Medicines
  - Available for use as an Excipient Ingredient in: Prescription Medicines
  - Not available as an Equivalent Ingredient in any application
- As of 11 June 2024, there were 9 medicines currently active on the Australian Register of Therapeutic Goods (ARTG) that contain *Atropa belladonna* in any form as an active ingredient. These include no prescription and nine non-prescription medicines with three different sponsors. Of these 9 preparations, 4 are oral preparations.
- The oral preparations that are available are homeopathic.
- According to the Therapeutic Goods (Permissible Ingredients) Determination (No.1) 2024, *Atropa belladonna* is permitted to be included in listed medicines as follows:

Item	Ingredient name	Purpose	Specific requirements
737	ATROPA BELLADONNA	A, H	Alkaloids calculated as hyoscyamine and atropine are mandatory components of Atropa belladonna. The concentration of alkaloids calculated as hyoscyamine in the medicine must be no more than 300 micrograms/kg or 300 micrograms/L or 0.00003%. The concentration of atropine in the medicine must be no more than 100 micrograms/kg or 100 micrograms/L or 0.00001%.
A = active ingredient for a medicine has the same meaning as in the Regulations H = homeopathic preparation ingredient meaning an ingredient that is a constituent of a homeopathic preparation			

- The TGA prescribing medicines in pregnancy database classifies *Atropa belladonna* as:

Drug name	Category	Classification Level 1	Classification Level 2	Classification Level 3
belladonna	B2	Cholinergic and Anticholinergic Agents		

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.

- The Therapeutic Goods (Medicines Advisory Statements) Specification 2021 requires the following warning statements pertaining to [Substance] to be included on the labelling:

Substance	Conditions	Required Statement(s)
Atropa belladona	In preparations for oral use, EXCEPT where indicated exclusively for the treatment of motion/travel sickness	If the condition persists after 2 days of treatment, seek medical advice

- As of August 2024, there were 62 reports of adverse events for products containing *Atropa belladonna* as an active ingredient on the Database of Adverse Events Notifications (DAEN), with 62 reports where *Atropa belladonna* was the single suspected medicine. From 2013, 6 reports have been received and 4 of those in the last 12 months to May 2024.
- There were no reports of deaths associated with *Atropa belladonna* use in Australia.
- As of June 2024, there was one product containing *Atropa belladonna* as an active ingredient/constituent or scheduled *Atropa belladonna* listed on the Public Chemical Registration Information System Search (PubCRIS).
- There were no adverse experiences were recorded for *Atropa belladonna* in the APVMA Adverse Experience Reporting Program database (AERP) from 2014-2023.

International regulations

- In September 2016, the FDA warned against the use of homeopathic teething tablets and gels containing belladonna, a toxic *Atropa belladonna* that has an unpredictable response in children under two years of age, after the products were associated with serious adverse events, including seizures and deaths, in infants and children. An FDA lab analysis later confirmed that certain homeopathic teething tablets contained elevated and inconsistent levels of belladonna. A similar issue occurred in 2010.
- An FDA report indicated that "Inconsistency in levels of belladonna, a toxic *Atropa belladonna*, signals a poorly controlled manufacturing process and poses an unnecessary risk to infants and children under two years of age."
- Medsafe - New Zealand lists both hyoscyamine, a component of *Atropa belladonna*, and *Atropa belladonna* as follows:

Ingredient	Conditions (if any)	Classification
Hyoscyamine	**except** when specified elsewhere in this schedule; **except** in medicines containing 300 micrograms or less per litre or per kilogram	Prescription

Hyoscyamine	for external use in medicines containing 0.03% or less of total solanaceous alkaloids; for oral use in liquid form in medicines containing 0.03% or less and 0.3 milligrams or less per dose and not more than 1.2 milligrams per recommended daily dose of total solanaceous alkaloids; in solid dose form in medicines containing 0.3 milligrams or less per dose form and not more than 1.2 milligrams per recommended daily dose of total solanaceous alkaloids	Pharmacy Only
Atropa belladonna	**except** when specified elsewhere in this schedule; **except** in medicines containing 300 micrograms or less of total solanaceous alkaloids per litre or per kilogram	Prescription
Atropa belladonna	for external use in medicines containing 0.03% or less of the alkaloids of belladonna; for oral use in liquid form in medicines containing 0.03% or less and 0.3 milligrams or less per dose and not more than 1.2 milligrams per recommended daily dose of the alkaloids of belladonna or in solid dose form in medicines containing 0.3 milligrams or less per dose form and not more than 1.2 milligrams per recommended daily dose of the alkaloids of belladonna	Pharmacy Only

- Health Canada has several active homeopathic products containing belladonna which are listed as natural products.
- The Health Products Regulatory Authority in Ireland has one authorised product containing *Atropa belladonna*. It does not require a medical prescription.

Pyridoxine, pyridoxal or pyridoxamine (vitamin B_6)

Proposal

The applicant has proposed to amend the current Poisons Standard in relation to pyridoxine, pyridoxal and pyridoxamine which are different forms of vitamin B6. Under the proposal, human therapeutic preparations containing between 5 mg and 200 mg of pyridoxine, pyridoxal or pyridoxamine would be included in a new Pharmacist Only Medicine (Schedule 3) entry. These preparations are currently exempted from Schedule 4 and are not scheduled otherwise.

CAS number

65-23-6 (Pyridoxine)

66-72-8 (Pyridoxal)

85-87-0 (Pyridoxamine)

Alternative names

Vitamin B6

Applicant

Private applicant

Proposed Scheduling

Pyridoxine, pyridoxal or pyridoxamine for human therapeutic use are currently scheduled as a Prescription only medicines (Schedule 4) except:

(a) in oral preparations containing 200 mg or less but more than 50 mg of pyridoxine, pyridoxal or pyridoxamine per recommended daily dose when compliant with the requirements of the required advisory statements for medicine labels; or
(b) in oral preparations containing 50 mg or less of pyridoxine, pyridoxal or pyridoxamine per recommended daily dose.

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

Schedule 4 – Amend Entry

PYRIDOXINE, PYRIDOXAL OR PYRIDOXAMINE for human therapeutic use except when included in Schedule 3.

~~(a) in oral preparations containing 200 mg or less but more than 50 mg of pyridoxine, pyridoxal or pyridoxamine per recommended daily dose when compliant with the requirements of the required advisory statements for medicine labels; or~~

~~(b) in oral preparations containing 50 mg or less of pyridoxine, pyridoxal or pyridoxamine per recommended daily dose.~~

Schedule 3 – New Entry

PYRIDOXINE, PYRIDOXAL OR PYRIDOXAMINE for human therapeutic use when in oral preparations containing 200 mg or less but more than 5 mg of pyridoxine, pyridoxal or pyridoxamine per recommended daily dose when compliant with the requirements of the required advisory statements for medicine labels.

Index – Amend Entry

PYRIDOXINE, PYRIDOXAL OR PYRIDOXAMINE

Schedule 4
Schedule 3

Background

Vitamin B6 is a water-soluble, essential nutrient found in food. It acts as a co-enzyme in numerous enzymatic reactions in the metabolism of amino acids, carbohydrates and lipids. Vitamin B6 is also important for the synthesis of many neurotransmitters, haemoglobin formation and immune functions.

Vitamin B6 refers to 6 compounds with vitamin B6 activity: pyridoxine, pyridoxal, pyridoxamine and each of their 5'-phosphate esters. Pyridoxine hydrochloride, pyridoxal 5'-phosphate, and pyridoxal 5'-phosphate monohydrate are available for use in listed medicines.

Accumulation of vitamin B6 through supplemental intake can cause peripheral neuropathy, which has symptoms of tingling, burning or numbness, usually in the hands or feet. It usually occurs at high doses or following long-term use of products containing vitamin B6, especially when people are taking multiple products containing vitamin B6. Peripheral neuropathy can also occur at low doses.

Summary of applicant's reasons for the proposal

- In the applicant's opinion, increasing number of patients are presenting with vitamin B6 toxicity that is causing progressive and often severe nerve damage.
- Vitamin B6 (pyridoxine) is present in numerous multivitamin and mineral supplements that can be bought in supermarkets, health food shops and pharmacies without a prescription.
- The applicant stated that many people are not aware that vitamin B6 can cause peripheral neuropathy.

- The application stated that consumers are self-medicating by using these supplements and taking more than more than one tablet daily from multiple sources. Examples include magnesium supplements to control muscle cramps or taking several supplements each of which contain vitamin B6.
- While products containing a daily dose of vitamin B6 above 10 mg require a warning about peripheral neuropathy, consumers often do not read the warnings.
- Further, elderly patients who receive a vitamin B6-containing supplement included in a Webster Pack[5] do not have the opportunity to see the warnings.
- Ceasing the vitamin B6 containing supplement may result in the condition improving, however, for many, the damage is permanent and stopping the supplement will only prevent further damage.

Key uses

Vitamin B6 is commonly present in products such as multivitamins, vitamin B complexes and mineral preparations – often in combination with magnesium or zinc.

It is generally used as a nutritional supplement by the public for a variety of perceived health benefits, including morning sickness, cardiovascular disease, premenstrual syndrome, depression and carpal tunnel syndrome.

Clinical deficiency of vitamin B6 is rare.[6] Vitamin B6 supplementation is a therapeutic option for a variety of medical conditions, for example, seizures from isoniazid toxicity and intractable vomiting during pregnancy.

Intake from food-based sources of pyridoxine do not cause toxicity.[7]

Australian regulations

- According to the TGA Ingredient Database, vitamin B6 is available as active, excipient or equivalent ingredient in a number of applications.

	Active ingredient	Excipient ingredient	Equivalent ingredient
Pyridoxine	Biologicals, Export Only, Over the Counter, Prescription Medicines	Biologicals, Devices, Export Only, Over the Counter, Prescription Medicines	Export Only, Listed Medicines, Prescription Medicines
Pyridoxine hydrochloride	Biologicals, Export Only, Listed Medicines, Over the Counter, Prescription Medicines	Biologicals, Devices, Export Only, Listed Medicines, Over the Counter, Prescription Medicines	Not available in any application
Pyridoxal hydrochloride	Biologicals, Prescription Medicines	Biologicals, Devices, Prescription Medicines	Not available in any application
Pyridoxal 5-phosphate	Biologicals, Export Only, Listed Medicines, Over the Counter, Prescription Medicines	Biologicals, Devices, Listed Medicines, Prescription Medicines.	Not available in any application

[5] A Webster Pack helps those taking medication to take the right dose at the right time and manage complex medication regimes

[6] Vitamin B6 | Eat For Health (viewed 27 August 2024)

[7] Vitamin B6 Toxicity - StatPearls - NCBI Bookshelf (nih.gov), 2023 (viewed 27 August 2024)

Pyridoxal 5-phosphate monohydrate	Export Only, Listed Medicines, Over the Counter, Prescription Medicines	Not available in any application.	Not available in any application.

Note: Pyridoxine hydrochloride is available as homoeopathic ingredient in Listed Medicines while pyridoxal 5-phosphate and pyridoxal 5-phosphate monohydrate are not.

- Currently there are more than 1,500 medicines in Australia that contain vitamin B6 as an active ingredient. Most of these are health supplements that can be bought in supermarkets, health foods stores and pharmacies without a prescription and are classified as listed medicines. There are also 7 registered complementary medicines and 10 prescription medicines.
- According to the Therapeutic Goods (Permissible Ingredients) Determination (No. 2) 2024, pyridoxine hydrochloride, pyridoxal 5-phosphate, and pyridoxal 5-phosphate monohydrate are available for use in listed medicines as follows:
  - pyridoxine hydrochloride: active ingredient, excipient
  - pyridoxal 5-phosphate: active ingredient
  - pyridoxal 5-phosphate monohydrate: active ingredient, excipient and homeopathic ingredient.
- The following restrictions apply when pyridoxine hydrochloride, pyridoxal 5-phosphate, and pyridoxal 5-phosphate monohydrate are used in listed medicines.
  - Pyridoxine is a mandatory component of pyridoxal 5-phosphate, the percentage for which should be calculated based on the molecular weight of the above permissible ingredients.
  - The maximum recommended daily dose of the medicine must not provide more than:
    a) 15 mg of pyridoxine for children aged between 1 and 3 years (inclusive)
    b) 20 mg of pyridoxine for children aged between 4 and 8 years (inclusive)
    c) 30 mg of pyridoxine for children aged between 9 and 13 years (inclusive)
    d) 40 mg of pyridoxine for individuals aged 14 and 18 years (inclusive)
    e) 100 mg of pyridoxine for individuals aged 19 years and older
  - If the maximum recommended daily dose of the medicine provides more than 10 mg of pyridoxine, the following warning statement is required on the medicine label:

    (VITB6SX) 'WARNING - Stop taking this medication if you experience tingling, burning or numbness and see your healthcare practitioner as soon as possible. [Contains vitamin B6].
- Vitamin B6 is not included in TGA prescribing medicines in pregnancy database
- The Therapeutic Goods (Medicines Advisory Statements) Specification 2021 requires the following warning statements pertaining to vitamin B6 (pyridoxine or pyridoxal) to be included on the labelling:

Substance	Conditions	Required Statement(s)
Vitamin B6 pyridoxal pyridoxine	In SINGLE-INGREDIENT preparations containing 200 mg or less but more than 50 mg of [pyridoxine / pyridoxal] per recommended daily dose	WARNING – Stop taking this medication if you experience tingling, burning or numbness and see your healthcare practitioner as soon as possible.

Vitamin B6 pyridoxal pyridoxine	In MULTI-INGREDIENT preparations containing 200 mg or less but more than 50 mg of [pyridoxine / pyridoxal] per recommended daily dose	WARNING – Stop taking this medication if you experience tingling, burning or numbness and see your healthcare practitioner as soon as possible. -Contains vitamin B6.

- As of 20 August 2024, there were 113 reports of peripheral neuropathy, peripheral sensory neuropathy, small fibre neuropathy or chronic polyneuropathy for products containing vitamin B6 on the Database of Adverse Event Notifications (DAEN). The majority of these adverse events were reported since 2023.
  - 55 of these also reported 'Hypervitaminosis B6' and/or 'Vitamin B6 increased'
  - an additional 71 cases reporting 'Hypervitaminosis B6' and/or 'Vitamin B6 increased' some of which also reported symptoms of peripheral neuropathy but used other reaction terms (such as paraesthesia, burning sensation etc.).
- As of 25 August 2024, there were 23 products containing vitamin B6 as an active ingredient listed on the Public Chemical Registration Information System Search (PubCRIS).
- Between 2015-16 and 2019-2011 adverse experience related to animal health was recorded for vitamin B6 in the APVMA Adverse Experience Reporting Program database (AERP).
- The Nutrient Reference Values for Australia and New Zealand for vitamin B6 published by the National Health and Medical Research Council establish appropriate upper levels of intake of 50 mg pyridoxine per day from all sources.
- As of August 2024, pyridoxine and pyridoxal 5'-phosphate and pyridoxal phosphate, monohydrate are listed on the Australian Inventory of Industrial Chemicals. Pyridoxamine is not listed.

International regulations

- In Canada vitamin B6 is available as dietary supplement without a prescription that are regulated as natural and non-Prescription health products. The Licensed Natural Health Products Database includes 33 active products. The maximum daily dose of vitamin B6 that can be provided by any of these supplements is 50 mg/day.
- Vitamin B6 is also available as ethical (unscheduled non-prescription products that are used by professionals) and prescription medicines. The Health Canada Drug Product Database 11 products containing pyridoxine that are currently marketed. Of these 11, there are 3 ethical products and 8 are prescription medicines.
- The New Zealand Medsafe Medicines Classification Database lists pyridoxine as follows:

Ingredient	Conditions (if any)	Classification
Pyridoxine	in medicines containing more than 200 milligrams per recommended daily dose	Prescription
Pyridoxine	in medicines containing 200 milligrams or less per recommended daily dose	General sale

- In the US, vitamins are commonly available as dietary supplements. However, a complete list of all dietary supplements sold in the United States is not available from the Food and Drug

Administration. The US Food and Drug Administration's Orange Book includes 11 prescription-only medicines that are currently available.

- Ireland's Health Products Regulatory Authority regulates 10 products containing pyridoxine hydrochloride. All are available for supply through pharmacies only and 9 require prescription.
- In the UK, vitamins are available as food supplements where the use is not intended to treat or prevent diseases in humans or to modify physiological functions. Vitamin B6 is permitted for use in the manufacture of food supplements. Supplements providing more than 10 mg vitamins B6 per day are required to have a label warning statements regarding possible mild tingling and numbness from long term use.
- The UK electronic medicines compendium (emc) lists 6 prescription only medicines and one pharmacy only medicine containing vitamin B6. Only one medicine is available for general sale that provides 2 mg vitamin B6 per 5 ml syrup.
- The regulatory approach for acceptable levels and warnings varies internationally.
  - The European Food Safety Authority established a daily upper limit for supplemental pyridoxine of 25 mg/day
  - The US Food and Drugs Administration and Health Canada set an upper safe limit of 100 mg/day
  - The Association of Southeast Asian Nations recommends a maximum limit of 100 mg/day vitamin B6. However, Thailand has implemented its own limit of 2 mg/day.
  - The Expert Group on Vitamins and Minerals UK (EVM), of the Medicines and Healthcare products Regulatory Agency UK, established a safe upper limit for daily consumption of vitamin B6 10 mg/day for a 60 kg human adult.

Proposed amendment referred for scheduling advice to Joint ACMS-ACCS meeting #38

Ethylene oxide, propylene oxide and epichlorohydrin

Proposal

This application proposes a low-concentration cut-off be added to the Dangerous Poison (Schedule 7) entries for ethylene oxide, propylene oxide and epichlorohydrin. The proposal will enable preparations containing trace amounts of ethylene oxide, propylene oxide and epichlorohydrin to be exempted from scheduling.

CAS number

75-21-8 (ethylene oxide)

75-56-9 (propylene oxide)

106-89-8 (epichlorohydrin)

Alternative names

Ethylene oxide: 1,2-epoxyethane; oxirane, oxacyclopropane; epoxyethane; dimethylene oxide; dihydrooxirene; ETO; ethene oxide; oxidoethane.
Propylene oxide: methyl oxirane; 1,2-epoxypropane , propylene epoxide; methyl ethylene oxide;
Epichlorohydrin: ethylene chlorohydrin; ECH, 2-(chloromethyl)oxirane; 1-chloro-2,3-epoxypropane; chloro-1,2-propylene oxide; oxirane, (chloromethyl)-

Applicant

Private applicant

Proposed scheduling

The applicant's proposed amendments to the Poisons Standard are:[8]

Schedule 7 – Amend Entry

ETHYLENE OXIDE except in preparations containing less than 0.002%

Index

ETHYLENE OXIDE

Schedule 7 – Amend Entry

PROPYLENE OXIDE except in preparations containing less than 0.002%

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PROPYLENE OXIDE

[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.

Schedule 7 – Amend Entry

EPICHLOROHYDRIN except in preparations containing less than 0.002%

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EPICHLOROHYDRIN

Background

Ethylene oxide is a fumigant registered for use to reduce microbials on whole and ground spices or other seasoning materials, and to fumigate beekeeping equipment (for example, wooden ware, boxes and frames).Other uses of ethylene oxide include the fumigation/sterilisation of medical or laboratory equipment, pharmaceuticals, and aseptic packaging; or to reduce the microbial load on cosmetics; and to sterilise artifacts, archival material, library objects, and musical instruments. It is applied by commercial applicators only; there are no residential uses of ethylene oxide.

Propylene oxide is used in the production of polyethers (the primary component of polyurethane foams) and propylene glycol.

Epichlorohydrin is mainly used in the production of epoxy resins[9].

Summary of applicant's reasons for the proposal

- Ethylene oxide, propylene oxide and epichlorohydrin are Dangerous poison (Schedule 7) substances with no cut-off concentration or use exemption. They are used in the manufacture of poly-ethoxylated surfactants. Consequently, these substances can be present as a trace impurity in many commonly used surfactants, for example, alkylphenol ethoxylates. Under the Poisons Standard, products using these surfactants are classified as a Dangerous Poison (Schedule 7).
- These substances can be present in raw materials as impurities up to a maximum level of 10 ppm. The levels of ethylene oxide residue in an ethoxylated surfactant would depend on the level of ethoxylation which leads to different characteristics across surfactants. A low level cut off of 20 ppm has been suggested to avoid the need for batch testing of every batch of highly ethoxylated surfactants as a raw material, to comply with a 10 ppm limit.
- Poly-ethoxylated surfactants will then be formulated into a range of products with the levels dependant on the amount of surfactant in the formulation. The benefits of surfactants in a range of products is well understood. For example, hand washing with surfactant-based products is key to infection control.
- However, the presence of these substances as impurities in surfactants is unavoidable and occurs in a range of products on the Australian market and internationally.
- Examples of residual levels of ethylene oxide are:
  - Cleaning products: 1-5 ppm
  - Toothpaste: less than 1 ppb
  - Personal care products: less than 1 ppb
  - Air fresheners: less than 1 ppb
  - Therapeutic goods: less than 1 ppb

[9] Epichlorohydrin | C3H5ClO | CID 7835 - PubChem (nih.gov) (viewed 13/9/2024)

- Trace levels of ethylene oxide in surfactants and products containing these surfactants do not present a risk to human health.
- As the Poisons Standard considers risks and benefits of substances, an additional low level cut off aligns with the scheduling factors.
- The impurity levels of trace compounds in surfactants and products are also controlled by other regulators in Australia, for example, in therapeutic good by the TGA and in consumer products by ACCC. The applicant states that a lack of a low level cut off creates over regulation of surfactants and downstream products that contain tiny amounts of impurities.
- The surfactants that contain these impurities do not meet the Schedule 7 factors and it may be more appropriate to consider each Schedule 7 surfactant substance separately as the need arises.

Key uses / expected use

Ethylene oxide, propylene oxide and epichlorohydrin are present at low levels in a large range of products. They are incorporated during manufacturing and fumigating processes.

Ethylene oxide is a necessary component in the production of surfactants that are widely used in products for many industries such as healthcare, industrial and domestic cleaning, personal care and specialty products. Raw material used in the manufacture of chemical derivatives, sterilant, fumigant, insecticide.

Propylene oxide is a raw material used in the manufacture of chemical derivatives, a stabiliser and a solvent.

Epichlorohydrin is a chemical intermediate used in a variety of applications, including epoxy resins, textiles, paper products, inks, dyes, automotive and aircraft parts, biocides, personal care products, and ion-exchange resins.

Australian regulations

- According to the TGA Ingredient Database, ethylene oxide is:
  - Available for use as an Active Ingredient in Biologicals, and Prescription Medicines
  - Available for use as an Excipient Ingredient in Biologicals, Devices and Prescription Medicines/Not available as an Excipient Ingredient in any application
  - Available for use as an Equivalent Ingredient in Export Only and Listed Medicines
- According to the TGA Ingredient Database, propylene oxide is:
  - Not available for use as an Active Ingredient in any application
  - Available for use as an Excipient Ingredient in: Export Only
  - Not available as an Equivalent Ingredient in any application
- According to the TGA Ingredient Database, epichlorohydrin is not listed for use.
  - Not available for use as an Active Ingredient in any application
  - Available for use as an Excipient Ingredient in: Export Only
  - Not available as an Equivalent Ingredient in any application

- As of September 2024, there were no medicines currently active on the Australian Register of Therapeutic Goods (ARTG) that contain ethylene oxide, propylene oxide or epichlorohydrin as an active ingredient.
- Propylene oxide is not permitted to be included in listed medicines as it is not listed in the Therapeutic Goods (Permissible Ingredients) Determination (No.2) 2024.
- According to the Therapeutic Goods (Permissible Ingredients) Determination (No.2) 2024, propylene oxide is not permitted to be used in listed medicines but ethylene oxide and epichlorohydrin are permitted with certain restrictions (below):

Ingredient name	Purpose	Specific requirements
BEHENETH-10	E	Only for use in topical medicines for dermal application and not to be included in topical medicines intended for use in the eye. The concentration in the medicine must be no more than 1.5%. Residual levels of ethylene oxide are to be kept below the level of detection.
C11-14-ISO-ALCOHOL C-13 RICH	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.125%. Residual levels of 1,4-dioxane and ethylene oxide (and related substances) are to be kept below the level of detection.
C12-13 PARETH-3	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.125%. Residual levels of 1,4-dioxane and ethylene oxide (and related substances) are to be kept below the level of detection.
LAURETH-2	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.4%. Residual levels of ethylene oxide (and related substances) must be kept below the level of detection.
LAURYL PEG/PPG-18/18 METHICONE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 9%. Residual levels of ethylene oxide (and related substances) must be kept below the level of detection.
METHYL GLUCETH-10	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 3%. Residue levels of ethylene oxide are to be kept below the level of detection.
OCTYLDODECETH-25	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 5%. Residual levels of 1,4-dioxane and ethylene oxide (and related substances) are to be kept below the level of detection.
OLETH-2	E	Only for use in topical medicines for dermal application. Dioxane and ethylene oxide are mandatory components of Oleth-2. The concentration of ethylene oxide in the medicine must be no more than 1 mg/kg or 1 mg/L or 0.0001%.

PEG-4 LAURATE	E	Only for use in topical medicines for dermal application. Dioxane and Ethylene oxide are mandatory components of PEG-4 laurate. The concentration of ethylene oxide in the medicine must be no more than 1 mg/kg or 1 mg/L or 0.0001%.
PEG-40 SORBITAN DIISOSTEARATE	E	Only for use in topical medicines for dermal application. Dioxane and ethylene oxide are mandatory components of PEG-40 sorbitan diisostearate. The concentration of dioxane in the medicine must be no more than 10 mg/kg or 10 mg/L or 0.001%. The concentration of ethylene oxide in the medicine must be no more than 1 mg/kg or 1 mg/L or 0.0001%.
GLYCERYL STARCH	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 4%. The residual levels of epichlorohydrin are to be kept below the level of detection.

- Ethylene oxide, propylene oxide and epichlorohydrin are not medicines and, as such, are not included in the TGA prescribing medicines in pregnancy database.
- There are no warning statements pertaining to ethylene oxide, propylene oxide or epichlorohydrin in the Therapeutic Goods (Medicines Advisory Statements) Specification 2021.
- As of August 2024, there were no reports of adverse events for products containing ethylene oxide, propylene oxide or epichlorohydrin as an active ingredient on the Database of Adverse Events Notifications (DAEN).
- As of September 2024, there were no products containing epichlorohydrin as an active ingredient/constituent or scheduled substance listed on the Public Chemical Registration Information System Search (PubCRIS).
- As of September 2024, there were 21 products containing ethylene oxide as an active ingredient/constituent listed on the Public Chemical Registration Information System Search (PubCRIS).
  - These products are surfactants, wetting agents, fumigants (mixed function pesticides) and one miticide.
- As of September 2024, there was 1 product containing propylene oxide as an active constituent listed on the Public Chemical Registration Information System Search (PubCRIS).
- In 2010-2020 the no adverse experiences were recorded for ethylene oxide, propylene oxide or epichlorohydrin in the APVMA Adverse Experience Reporting Program database (AERP).
- Ethlylene oxide, propylene oxide and epichlorohydrin are included in the Australian Inventory of Industrial Chemicals.

International regulations

- Ethylene oxide is listed as an antimicrobial under the United States Environmental Protection Agency's (US EPA) Office of Pesticides Program
- The Occupational Safety and Health Administration (OSHA) regulates worker exposure to ethylene oxide in the USA.[Note that limits in specialised workplaces are often set higher than those for general public exposure]
  - In 1984, OSHA reduced the permissible exposure limit from 50 ppm to 1 ppm.

  - In 1988, OSHA established a short-term exposure limit (STEL) of 5 ppm for exposures up to 15 minutes.[10]
  - In 1996, EPA required pesticide product label improvements to standardise precautionary statements, specify items to be treated with ethylene oxide, and require all users to adopt OSHA's risk reduction measures.

- Epichlorohydrin is toxic to humans *via* multiple routes and is a potential carcinogen. The accurate measurement of epichlorohydrin at trace level (<0.1 µg/L or <0.001 ppm) is still an obstacle hindering the monitoring and regulation of municipal water systems in the USA.[11]
- The European Agency for the Evaluation of Medicinal Products has the following specifications in their Note For Guidance On Limitations To The Use Of Ethylene Oxide In The Manufacture Of Medicinal Products:
  - The limits are fixed on a mass/mass basis and not on a daily intake basis. If no official test procedure (e.g. Pharmacopoeia) is available a validated test procedure must be proposed by the applicant (see also note for guidance on Validation of Analytical Procedures Methodology).
  - **Raw materials Specification:** Ethylene oxide: 1 µg/g (1 ppm) Ethylene chlorhydrin (or any other halogenated ethylenehydrine): 50 µg/g (50 ppm).
  - **Finished product:** If the residual ethylene oxide originates from its use in the raw starting material, its content must be limited in the raw starting material. Specification (when used on the finished product): Ethylene oxide: 1 µg/g (1 ppm) Ethylene chlorhydrin (or any other halogenated ethylenehydrine): 50 µg/g (50 ppm).
  - **Containers Specification (based on simulated use):** Ethylene oxide: 1 µg/ml (1 ppm)(container volume) Ethylene chlorhydrin (or any other halogenated ethylenehydrine): 50 µg/ml (50 ppm) (container volume)

[10] https://www.regulations.gov/document/EPA-HQ-OPP-2013-0244-0017 (viewed 12 September 2024)

[11] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9553001/#:~:text=Epichlorohydrin%20(ECH)%20is%20toxic%20to,regulation%20of%20municipal%20water%20systems.

Symphytum officinalis (comfrey)

Proposal

The applicant has proposed to amend the Poisons Standard in relation to topical *Symphytum* spp (comfrey) to allow dermal preparations for therapeutic or cosmetic use to be unscheduled when containing concentrations of 20% or less of comfrey.

CAS number

84696-05-9 (*Symphytum Officinale* Leaf Extract)

Alternative names

Comfrey, boneset, knitbone, black wort, wall wort, slippery root

Applicant

Private applicant

Proposed scheduling

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

Schedule 5 – Amend entry

SYMPHYTUM spp. in preparations for dermal therapeutic or dermal cosmetic use **except** in preparations for dermal therapeutic or dermal cosmetic use containing 20% or less of comfrey.

Schedule 10 – Amend entry

SYMPHYTUM spp. in preparations for human or animal use **except** when included or expressly excluded from Schedule 5.

Index

SYMPHYTUM spp.
cross reference: COMFREY

Schedule 10
Schedule 5
Appendix F, clause 4

Background

Topical preparations of comfrey are purported to treat pain, heal sprains, bruises, burns and joint inflammation, and to repair skin. In 1992 comfrey was listed in Schedule 5 for dermal use.

Liver toxicity associated with various potential uses of comfrey, including exposures via food, creams, ointments and in traditional medicines led to the revision of the Schedule 5 and Schedule 10 (previously Appendix C) entries in May 1992. This wording clarified the types of products included in the entries.

To reduce ambiguity, the Schedule 5 entry was further amended in 2016 to specifically include only dermal therapeutic products and dermal cosmetics.

In 2023, a proposal to include comfrey as a food with 0.9% alkaloids was not agreed to, due largely to the risk of liver toxicity.

Summary of applicant's reasons for the proposal

- The European Scientific Cooperative on Phytotherapy Monograph (ESCOP) monograph states that comfrey root can be used for tendinitis, knee joint injuries, gonarthrosis, fractures and skin inflammation. *Symphytum* species preparations have records of their traditional topical use in the treatment of musculoskeletal issues such as osteoarthritis (OA), back pain, ankle sprains, joint distortion, myalgia and rheumatism.
- Three topical products have been registered on the Australian Register of Therapeutic Goods (ARTG).
- Topical comfrey preparations are widely available in Europe, USA and New Zealand, where they are unscheduled.
- Pyrrolizidine alkaloids are considered not to be of clinical significance in topical products containing comfrey.[12]

Key uses / expected use

Medicines – topical

Australian regulations

- According to the TGA Ingredient Database, comfrey is:
  - Available for use as an Active Ingredient in: Export Only, Listed Medicines, Over the Counter, Prescription Medicines.
  - Available for use in Listed Medicines as a Homoeopathic Ingredient only
  - Available for use as an Excipient Ingredient in: Prescription Medicines.
  - Not available as an Equivalent Ingredient in any application.
- As of August 2024, there were 3 medicines currently active on the Australian Register of Therapeutic Goods (ARTG) that contain comfrey as an active ingredient. These are all non-prescription medicines.
- According to the Therapeutic Goods (Permissible Ingredients) Determination (No.4) 2023, *symphytum officinale* is permitted to be included in listed medicines as follows:

[12] Skin microbiota metabolism of natural products from comfrey root (Symphytum officinale L.) - PubMed (nih.gov) (viewed 28/8/2024)

Item	Ingredient name	Purpose	Specific requirements
4809	Comfrey Root Dry	H	When used orally as an active homoeopathic ingredient, the concentration must be a dilution of 12X or more. When used in topical medicines for dermal application, the concentration in the preparation must be no more than 10mg/kg or 10mg/L or 0.001%.
H = homeopathic preparation ingredient meaning an ingredient that is a constituent of a homeopathic preparation			

- Comfrey is not included in the TGA prescribing medicines in pregnancy database.
- The Therapeutic Goods (Medicines Advisory Statements) Specification 2021 requires the following warning statements pertaining to [Substance] to be included on the labelling:

Substance	Conditions	Required Statement(s)
Symphytum spp	In Schedule 5 to the current Poisons Standard	either **READ SAFETY DIRECTIONS.** [f] *or* **READ SAFETY DIRECTIONS BEFORE OPENING AND USING.** [f] SAFETY DIRECTIONS – -Do not use on broken skin – -Do not use under occlusive dressing. DO NOT SWALLOW. [g]
[f] = Statements must be included on the label written: (a) on a separate line or lines immediately below the cautionary statement "KEEP OUT OF REACH OF CHILDREN"; and (b) in bold-face sans serif capital letters of uniform thickness; and (c) in letters at least four tenths the height of the letters used for the signal words; and (d) with no other statement written on the same line		

- As of August 2024, there were 8 reports of adverse events for products containing comfrey as an active ingredient on the Database of Adverse Events Notifications (DAEN) with 7 reports where comfrey was the single suspected medicine. There was no report of deaths associated with comfrey use. The reported events associated with use of comfrey were diverse in nature and affected various organ classes/primarily related to hepatobiliary disorders, respiratory, application site reaction, thoracic and mediastinal disorders.

- As of August 2024, there was one product containing *Symphytum officinale*, as an active homeopathic ingredient listed on the APVMA Public Chemical Registration Information System Search (PubCRIS).

International regulations

- The European Commission database for information on cosmetic substances and ingredients database includes four marketed topical products containing leaf extract, root extract, root cell extract, and leaf powder. They are used as cosmetic ingredients for skin conditioning, anti-seborrheic treatment, soothing and as abrasives that do not require a prescription.
- The Health Canada Drug Product Database noted that the botanic species, with the exception of comfrey is listed as Ingredients that are prohibited for use in cosmetic products.

How to respond

Submissions must be provided by the closing date of 22 October 2024 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, unless marked confidential.

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.

Therapeutic Goods Administration

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