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

Consultation: Proposed amendments to the Poisons Standard – ACMS #50 and Joint ACMS-ACCS #44 meetings, July 2026

29 May 2026

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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 July 2026 meetings of the Advisory Committee on Medicines Scheduling (ACMS #50) and Joint Advisory Committee on Medicines and Chemicals Scheduling (Joint ACMS-ACCS #44). Submissions must be received by close of business 30 June 2026.

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) and a joint meeting of the ACMS and Advisory Committee on Chemicals Scheduling (ACCS).

This consultation closes on 30 June 2026

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 #50

1.1 Loratadine

Proposal

The applicant has proposed to amend the current Poisons Standard to increase the pack size of unscheduled loratadine (divided oral preparations containing 10 mg or less loratadine for the treatment of seasonal allergic rhinitis (SAR) in adults and children aged 6 years and over) from 10 dosage units to 30 dosage units. The proposal, if implemented, will allow for general sale of 30-packs of loratadine for the treatment of SAR in adults and children aged 6 years and over from retail stores and supermarkets. Currently, only 10-packs of loratadine are available through general sale.

CAS number

79794-75-5

Alternative names

4-(8-Chloro-5,6-dihydro-11H-benzo[5,6]cyclohepta[1,2-b]pyridin-11-ylidene)-1-piperidinecarboxylic acid ethyl ester

Applicant

Private applicant

Proposed Scheduling

Loratadine is currently listed in Schedules 4 and 2 of the Poisons Standard as follows:

Schedule 4

LORATADINE **except**:

(a) when included in Schedule 2; or

(b) in divided preparations for oral use for the treatment of seasonal allergic rhinitis in adults and children 6 years of age and over, when:

(i) in a primary pack containing 10 dosage units or less; and

(ii) labelled with a recommended daily dose not exceeding 10 mg of loratadine.

Schedule 2

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

(a) in a primary pack containing 10 dosage units or less when labelled for adults and children 6 years and over; and

(b) labelled with a recommended daily dose not exceeding 10 mg of loratadine.

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LORATADINE

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Loratadine is excluded from the entry for ANTIHISTAMINES under Appendix F, Clause 4 (Poisons that must be labelled with warning statements and safety directions) i.e. it does not require any warning statements and safety directions applicable to some other antihistamines.

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

Schedule 4 – Amend entry

LORATADINE **except**:

(a) when included in Schedule 2; or

(b) in divided preparations for oral use for the treatment of seasonal allergic rhinitis in adults and children 6 years of age and over when:

(i) in a primary pack containing ~~10~~30 dosage units or less; and
(ii) labelled with a recommended daily dose not exceeding 10 mg of loratadine.

Schedule 2 – Amend Entry

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

(a) in a primary pack containing ~~10~~30 dosage units or less when labelled for adults and children 6 years and over; and

(b) labelled with a recommended daily dose not exceeding 10 mg of loratadine.

Background

Loratadine is a long-acting, non-sedating second generation antihistamine, used for the treatment of both perennial and seasonal allergic rhinitis (SAR) and idiopathic chronic urticaria in adults and children 6 years of age and over. SAR affects approximately 1 in 4 Australians.[2]

SAR is characterised by an increased sensitivity to pollen, which is found in higher quantities in the atmosphere during spring and autumn months. The pollens cause degranulation of mast cells in the blood, releasing histamine. Histamine binds to cognate receptor proteins triggering physiological and inflammatory responses resulting in sneezing, runny nose, itchiness and watery eyes.

Loratadine binds to histamine H1 receptors and alleviates allergic symptoms by preventing endogenous histamine from binding to these receptors. Loratadine elicits little effect on the central nervous system due to its inability to cross the blood-brain barrier.[3] As a result, it does not produce the sedative and psychomotor effects seen with administration of first-generation antihistamines. This makes it a favourable option for everyday or ad-hoc use.

Since October 2017, 10-packs loratadine for adults and children over 6 years are available for general sale from retails and supermarkets.[4]

Summary of applicant's reasons for the proposal

The applicant argues in their proposal that loratadine, with its long history of safe use in Australia and well-defined toxicity profile, is suitable for wider availability in non-pharmacy settings such as supermarkets and convenience stores.

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[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.

[2] https://www.aihw.gov.au/reports/chronic-respiratory-conditions/allergic-rhinitis-hay-fever

[3] DrugBank (2026): Loratadine. Available at: https://go.drugbank.com/drugs/DB00455 [Accessed 14 May 2026]

[4] Final decisions & reasons for decisions by delegates of the Secretary to the Department of Health, 29 June 2017

As SAR is fairly common, easily self-identifiable and not typically mistaken for a more serious illness, the applicant believes that increasing access to loratadine, a medicine with favourable safety profile, will provide public health benefits.

The applicant also suggested that there is a strong preference for higher pack sizes, with consumers typically seeking larger quantities of the drug in a single purchase. The current 10-pack limit on general sale is inconvenient as SAR typically lasts for several weeks at a time. Furthermore, shorter pharmacy operating hours present a challenge for consumer access, whereas convenience stores and supermarkets allow consumers better, more flexible access to the medicine.

The applicant also argues that loratadine is widely available in packs of 30 dose units (and more) in non-pharmacy settings overseas. For example, the United States allows for the sale of up to 365 tablets of loratadine in supermarkets and the United Kingdom has a limit of 30 tablets for sales in non-pharmacy settings. As such, the applicant suggests that amending the scheduling of loratadine would align Australian regulations with the international ones.

Key uses / expected use

Loratadine is used for the treatment of SAR in adults and children.

Australian regulations

- According to the TGA Ingredient Database, loratadine is available for use as an active ingredient in: Biologicals, Export Only, Over the Counter and Prescription Medicines. It is available for use as an excipient ingredient in Biologicals, Devices and Prescription Medicines. It is not available as an equivalent ingredient in any application.
- As of 11 May 2026, there were 64 medicines currently active on the Australian Register of Therapeutic Goods (ARTG) that contain loratadine as an active ingredient. They are all non-prescription medicines.
- Loratadine is not permitted to be included in listed medicines as it is not included in the Therapeutic Goods (Permissible Ingredients) Determination No. 1 of 2026.
- The TGA prescribing medicines in pregnancy database classifies loratadine as:

Drug name	Category	Classification Level 1	Classification Level 2	Classification Level 3
Loratadine	B1	Allergy and Immune System	Antihistamines	–
Category B1 – 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 not shown evidence of an increased occurrence of foetal damage.				

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

Substance	Conditions	Required statements
Loratadine	In medicines for oral use	If you are pregnant or breastfeeding, check with your doctor or pharmacist before using this medicine.

- Between 1 January 2016 and 24 April 2026, there were 120 reports of adverse events for products containing loratadine as an active ingredient on the Database of Adverse Event Notifications (DAEN), with 45 reports where loratadine was the single suspected medicine. There were 2 reports of deaths associated with these reports of adverse events.

- As of 8 May 2026, there were no products containing loratadine as an active ingredient/constituent or scheduled substance listed on the Public Chemical Registration Information System Search (PubCRIS).
- Loratadine is not included by the Australian Industrial Chemicals Introduction Scheme (AICIS) on the Australian Inventory of Industrial Chemicals (Inventory).

International regulations

- The Health Canada Drug Product Database includes 16 approved/marketed drug products that contain loratadine as an active ingredient. This includes 1 product formulated in combination with pseudoephedrine sulfate.
- The New Zealand Medsafe Medicines Classification Database lists loratadine as follows:

Substance	Conditions (if any)	Classifications
Loratadine	**Except** when specified elsewhere in this schedule	Prescription
Loratadine	For oral use; **except** in divided solid dosage forms for oral use containing 10 milligrams or less per dose form for the treatment of seasonal allergic rhinitis when sold in the manufacturer's original pack containing not more than 10 days' supply	Pharmacy Only
Loratadine	In divided solid dosage forms for oral use containing 10 milligrams or less per dose form for the treatment of seasonal allergic rhinitis when sold in the manufacturer's original pack containing not more than 10 days' supply	General Sale

- The United Kingdom electronic medicines compendium lists 11 medicines containing loratadine 7 are of which are available for general sale (in non-pharmacy settings) in packs of up to 30 tablets at a maximum concentration of 10 mg per tablet.
- The United States Food and Drug Administration Approved Drug Products Database (Drugs@FDA) lists 49 medicines containing loratadine that are available over-the-counter. The Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations contains 48 listings available over-the-counter with loratadine as an active ingredient. In the United States, loratadine can be purchased from retail outlets including pharmacies, convenience stores and supermarkets at quantities exceeding 100 tablets.
- In the European Union, the Union Register of Medicinal Products lists 127 products containing loratadine as an active ingredient. Over-the-counter medicines, such as loratadine, are not available in any pack size outside of pharmacies in Europe.
- In Ireland, the Health Products Regulatory Authority lists 8 authorised medicines containing loratadine for human use. Antihistamines are not available in any pack size outside of pharmacies in Ireland.

1.2 Fexofenadine

Proposal

The applicant has proposed to amend the current Poisons Standard in relation to fexofenadine hydrochloride (fexofenadine). Currently, fexofenadine for the treatment of seasonal allergic rhinitis (SAR) in adults and children 12 years of age and over is available as Pharmacy medicine (Schedule 2) in packs of 10 dosage units, when providing not more than 10 days' supply at a maximum recommended daily dose (RDD) of 180 mg. Under the proposal, the pack size of such fexofenadine preparations would be increased from 10 tablets to 20 tablets and not more than 20

days' supply. This would allow packs of 20 fexofenadine tablets (180 mg RDD; maximum 20 days' supply) to be sold in non-pharmacy settings, such as supermarkets.

CAS number

153439-40-8

Alternative names

Carboxyterfenadine

Terfenadine carboxylate

4-[1-Hydroxy-4-[4-(hydroxydiphenylmethyl)-1- piperidinyl]butyl]-α,α-dimethyl-benzeneacetic acid

Applicant

Private applicant

Proposed Scheduling

Fexofenadine is currently listed in Schedules 4 and 2 of the Poisons Standard as follows:

Schedule 4

FEXOFENADINE **except**:

(a) when included in Schedule 2; or

(b) in divided preparations for the treatment of seasonal allergic rhinitis in adults and children 12 years of age and over when:

(i) in a primary pack containing 20 dosage units or less and not more than 10 days' supply; and

(ii) labelled with a recommended daily dose not exceeding 120 mg of fexofenadine; or

(c) for the treatment of seasonal allergic rhinitis in adults and children 12 years of age and over when:

(i) in a primary pack containing 10 dosage units or less and not more than 10 days' supply; and

(ii) labelled with a recommended daily dose not exceeding 180 mg of fexofenadine; or

(d) for the treatment of seasonal allergic rhinitis and children 6 years of age and over when:

(i) in a primary pack containing 20 dosage units or less and not more than 10 days' supply; and

(ii) labelled with a recommended daily dose not exceeding 60 mg of fexofenadine.

Schedule 2

FEXOFENADINE in preparations for oral use **except** in divided preparations:

(a) for the treatment of seasonal allergic rhinitis in adults and children 12 years of age and over when:

(i) in a primary pack containing 20 dosage units or less and not more than 10 days' supply; and

(ii) labelled with a recommended daily dose not exceeding 120 mg of fexofenadine; or

(b) for the treatment of seasonal allergic rhinitis in adults and children 12 years of age and over when:

(i) in a primary pack containing 10 dosage units or less and not more than 10 days' supply; and

(ii) labelled with a recommended daily dose not exceeding 180 mg of fexofenadine; or

(c) for the treatment of seasonal allergic rhinitis and children 6 years of age and over when:

(i) in a primary pack containing 20 dosage units or less and not more than 10 days' supply; and

(ii) labelled with a recommended daily dose not exceeding 60 mg of fexofenadine.

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FEXOFENADINE

Schedule 4

Schedule 2

Fexofenadine is excluded from the entry for ANTIHISTAMINES under Appendix F, Clause 4 (Poisons that must be labelled with warning statements and safety directions) i.e. it does not require any warning statements and safety directions applicable to some other antihistamines.

The applicant's proposed amendments to the Poisons Standard are:[5]

Schedule 4 – Amend Entry

FEXOFENADINE **except**:

(a) when included in Schedule 2; or

(b) in divided preparations for the treatment of seasonal allergic rhinitis in adults and children 12 years of age and over when:

(i) in a primary pack containing 20 dosage units or less and not more than ~~10~~20 days' supply; and

(ii) labelled with a recommended daily dose not exceeding ~~120~~180 mg of fexofenadine; or

~~(c) for the treatment of seasonal allergic rhinitis in adults and children 12 years of age and over when:~~

~~(i) in a primary pack containing 10 dosage units or less and not more than 10 days' supply; and~~

~~(ii) labelled with a recommended daily dose not exceeding 180 mg of fexofenadine; or~~

(~~d~~c) for the treatment of seasonal allergic rhinitis and children 6 years of age and over when:

(i) in a primary pack containing 20 dosage units or less and not more than 10 days' supply; and

(ii) labelled with a recommended daily dose not exceeding 60 mg of fexofenadine.

Schedule 2 – Amend Entry

FEXOFENADINE in preparations for oral use **except** in divided preparations:

(a) for the treatment of seasonal allergic rhinitis in adults and children 12 years of age and over when:

(i) in a primary pack containing 20 dosage units or less and not more than ~~10~~20 days' supply; and

(ii) labelled with a recommended daily dose not exceeding ~~120~~180 mg of fexofenadine; or

~~(b) for the treatment of seasonal allergic rhinitis in adults and children 12 years of age and over when:~~

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

~~(i) in a primary pack containing 10 dosage units or less and not more than 10 days' supply; and~~

~~(ii) labelled with a recommended daily dose not exceeding 180 mg of fexofenadine; or~~

(~~c~~b) for the treatment of seasonal allergic rhinitis and children 6 years of age and over when:

(i) in a primary pack containing 20 dosage units or less and not more than 10 days' supply; and

(ii) labelled with a recommended daily dose not exceeding 60 mg of fexofenadine.

Background

Fexofenadine is a second-generation antihistamine used for the treatment of seasonal allergic rhinitis (SAR) in adults and children 12 years of age and over. It also is used for the treatment of hives in children aged 6 months and over, dosed as an oral liquid preparation.

SAR is characterised by an increased sensitivity to pollen, producing symptoms such as sneezing, runny nose, itchiness in the trigeminal area and watery eyes. It affects approximately 1 in 4 Australians, as documented in the 2022 National Health Survey.[6]

Fexofenadine acts by blocking histamine H1 receptors in the body that mediate allergic responses and inflammation. The drug is highly selective for peripheral H1 histamine receptors and has very little off-target action. As it fails to cross the blood-brain barrier, it does not elicit the same effects on the central nervous system as first-generation antihistamines (such as sedation, anti-nausea and antiemesis) or impact psychomotor function.

Since May 2023, fexofenadine has been available in non-pharmacy settings in packs of 10 tablets, for concentrations of 180 mg or less based on its well-established history of safe use and availability of comparable products at a similar quantity.[7]

Summary of applicant's reasons for the proposal

The applicant argues that the availability of larger pack sizes in non-pharmacy settings will improve access and convenience, particularly for those who live in rural, regional and remote settings, and help to alleviate the economic burden associated with seasonal allergic rhinitis from diminished productivity. They also suggest that it will reduce unnecessary pharmacy visits and improve affordability for consumers during a period of economic uncertainty and increased cost of living pressures.

The applicant also highlights that fexofenadine possesses a favourable safety profile, with little risk of serious injury if taken in excess of the recommended daily dose. The applicant considered that SAR is easily self-diagnosable and most consumers who experience SAR are chronic sufferers. As a result, they are generally aware of how the illness presents and when to treat it with antihistamines. Whilst there is a risk of misdiagnosis of common colds for SAR, the applicant suggests that there is no risk of exacerbation of symptoms from treatment of colds with antihistamines.

Key uses / expected use

Fexofenadine is used for the treatment of SAR in adults and children.

Australian regulations

- According to the TGA Ingredient Database, fexofenadine hydrochloride is available for use as an active ingredient in: Biologicals, Export Only, Over the Counter and Prescription Medicines. It is available for use as an Excipient Ingredient in: Biologicals, Devices and Prescription Medicines.

[6] Australian Institute of Health and Welfare data on allergic rhinitis (hay fever). www.aihw.gov.au/reports/chronic-respiratory-conditions/allergic-rhinitis-hay-fever; accessed on 25 May 2026.

[7] Notice of final decision to amend (or not amend) the current Poisons Standard - ACMS #40, ACCS #34, Joint ACMS-ACCS #32, 3 May 2023 (updated 16 June 2023).

- As of 5 May 2026, there were 65 medicines currently active on the Australian Register of Therapeutic Goods (ARTG) that contain fexofenadine hydrochloride as an active ingredient. They are all non-prescription medicines.
- Fexofenadine is not permitted to be included in listed medicines as it is not included in the Therapeutic Goods (Permissible Ingredients) Determination No. 1 of 2026.
- The TGA prescribing medicines in pregnancy database classifies fexofenadine as:

Drug name	Category	Classification Level 1	Classification Level 2	Classification Level 3
Fexofenadine	B2	Allergy and Immune System	Antihistamines	–
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 fexofenadine to be included on the labelling:

Substance	Conditions	Required statements
Fexofenadine	In medicines for oral use	If you are pregnant or breastfeeding, check with your doctor or pharmacist before using this medicine.

- Between 1 January 2016 and 21 April 2026, there were 101 reports of adverse events for products containing fexofenadine as an active ingredient on the Database of Adverse Event Notifications (DAEN), with 48 reports where fexofenadine was the single suspected medicine. There was one reports of death associated with these reports of adverse events.
- As of 5 May 2026, there were no products containing fexofenadine as an active ingredient/constituent or scheduled substance listed on the Public Chemical Registration Information System Search (PubCRIS).
- Fexofenadine is not included by the Australian Industrial Chemicals Introduction Scheme (AICIS) on the Australian Inventory of Industrial Chemicals (Inventory).

International regulations

- The Health Canada Drug Product Database includes 4 non-prescription drugs containing fexofenadine hydrochloride.
- The New Zealand Medsafe Medicines Classification Database lists fexofenadine as follows:

Substance	Conditions	Classifications
Fexofenadine	**Except** for oral use	Prescription
Fexofenadine	For oral use **except** for the treatment of seasonal allergic rhinitis in adults and children 12 years of age and over when in capsules containing 60 milligrams or less of fexofenadine hydrochloride or in tablets containing 120 milligrams or less of fexofenadine hydrochloride with a maximum daily dose of 120 milligrams when sold in the manufacturer's original pack containing 20 dosage units or less and not more than 10 days' supply; for the treatment of seasonal allergic rhinitis in adults and	Pharmacy Only

Substance	Conditions	Classifications
	children 12 years of age and over when in tablets containing 180 milligrams or less of fexofenadine hydrochloride with a maximum daily dose of 180 milligrams when sold in the manufacturer's original pack containing 10 dosage units or less and not more than 10 days' supply	
Fexofenadine	For the treatment of seasonal allergic rhinitis in adults and children 12 years of age and over when in capsules containing 60 milligrams or less of fexofenadine hydrochloride or in tablets containing 120 milligrams or less of fexofenadine hydrochloride with a maximum daily dose of 120 milligrams when sold in the manufacturer's original pack containing 20 dosage units or less and not more than 10 days' supply; for the treatment of seasonal allergic rhinitis in adults and children 12 years of age and over when in tablets containing 180 milligrams or less of fexofenadine hydrochloride with maximum daily dose of 180 milligrams when sold in the manufacturer's original pack containing 10 dosage units or less and not more than 10 days' supply.	General Sale

- The Drugs@FDA: FDA-Approved Drugs database contains 70 products with fexofenadine as an active ingredient. Of these 70 products, 25 have been discontinued and 6 have received tentative approval for commercial sale. The Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations contains 90 entries with fexofenadine as an active ingredient. In the United States, antihistamines are typically available for purchase in non-pharmacy settings, such as supermarkets, in quantities exceeding 100 tablets.
- Fexofenadine is not listed in the Union Register of medicinal products - Public health - European Commission, however, terfenadine (the active metabolite of fexofenadine) has 44 entries in the Register. Antihistamines are not available for sale in non-pharmacy settings (such as supermarkets) in the European Union.
- The United Kingdom's Electronic Medicines Compendium lists 21 products containing fexofenadine that are currently available. Fexofenadine is available in non-pharmacy settings in pack sizes of up to 30 tablets, at a strength of 120 mg per tablet.
- In Ireland, the Health Products Regulatory Authority lists 11 products authorised for human use that contain fexofenadine as an active ingredient. Antihistamines are not available for sale in non-pharmacy settings (such as supermarkets) in Ireland.

1.3 Pseudoephedrine

Proposal

This application proposes an amendment to the current Poisons Standard in relation pseudoephedrine to allow the advertising of Pharmacist only (Schedule 3) preparations of pseudoephedrine by including the substance in Appendix H (Schedule 3 medicines permitted to be advertised). Pseudoephedrine preparations are Pharmacist only (Schedule 3) or Prescription only (Schedule 4) medicines depending on purpose and formulation. The proposal does not intend to change the scheduling of pseudoephedrine otherwise i.e. the existing controls on access and supply are retained while allowing the advertising of Pharmacist only pseudoephedrine medicines to consumers.

CAS numbers:

CAS 90-82-4 (pseudoephedrine)

CAS 345-78-8 (pseudoephedrine hydrochloride)

Alternative names

(1S,2S)-2-methylamino-1-phenylpropan-1-ol

D-isoephedrine

D-ψ-ephedrine

Applicant

Private applicant

Proposed Scheduling

Pseudoephedrine is currently listed in Schedules 3 and 4 of the Poisons Standard as follows:

Schedule 3

PSEUDOEPHEDRINE (other than preparations for stimulant, appetite suppression or weight-control purposes) when supplied in a primary pack:

(a) in liquid preparations containing 800 mg or less of pseudoephedrine hydrochloride (or its equivalent); or

(b) in other preparations containing 720 mg or less of pseudoephedrine hydrochloride (or its equivalent).

Schedule 4

PSEUDOEPHEDRINE except when included in Schedule 3.

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PSEUDOEPHEDRINE

Schedule 4
Schedule 3

The applicant proposes to create a new Appendix H entry without any changes to Schedule 3 and Schedule 4 entries.[8]

Appendix H – New Entry

PSEUDOEPHEDRINE

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PSEUDOEPHEDRINE

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Appendix H

Background

Pseudoephedrine is indicated for symptomatic relief of nasal congestion associated with colds, influenza, and allergic rhinitis (hay fever) and has been widely used as an oral, nasal and sinus decongestant for over 40 years in Australia. It reduces congestion in the upper respiratory tract, including the nose, nasal passages and sinuses, and making it easier to breathe.

Historically, pseudoephedrine was available as a Pharmacy medicine (Schedule 2) and could be advertised. In June 2005, due to concerns regarding its diversion for the illicit manufacture of methamphetamine, the National Drugs and Poisons Schedule Committee (NDPSC) rescheduled pseudoephedrine products to Schedule 3 and Schedule 4 (some higher-dose preparations), but advertising continued to be allowed. The arguments for retaining the Appendix H entry for

[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.

pseudoephedrine was reviewed by NDPSC In June 2010 and subsequently by the Advisory Committee on Medicines Scheduling (ACMS) in March 2011. Noting consumer awareness and existing supply arrangements, the committees considered that while advertising did not contribute to misuse, advertising did not provide enough public health benefit. Based on this advice, advertising of pseudoephedrine was disallowed from 1 June 2011.[9]

In Australia, the supply of pseudoephedrine is supported by Project STOP, which provides a real-time database for recording all requests for products containing pseudoephedrine. The program provides decision support to pharmacists, while also supplying real time data to law enforcement agencies and health regulators.

In some states and territories, it is mandatory for pharmacists to record the details of sales of over-the-counter packs of pseudoephedrine from community pharmacy in an online, real-time electronic form, at the time of supply.

Summary of applicant's reasons for the proposal

The applicant argues that pseudoephedrine is a well-established and effective decongestant with a known safety profile, and its risks are already managed through Schedule 3 controls and pharmacist oversight.

The applicant considered that current evidence indicates that the risk of diversion to illicit drug manufacture has diminished, with production now relying on alternative methods and precursors. Further, restrictions on advertising have not been shown to reduce misuse or methamphetamine use.

Based on the above, the applicant argues that permitting advertising would improve consumer awareness and support informed choice and pharmacist engagement, consistent with practices in comparable international jurisdictions where advertising is allowed without increased public health risk.

Key uses / expected use

Pseudoephedrine is used primarily for the relief of nasal and sinus congestion associated with conditions such as the common cold, influenza, and allergic rhinitis. It is supplied as both a single-ingredient product and in combination with other active ingredients, including analgesics, antitussives, and antihistamines, to provide multi-symptom relief in cold and flu preparations. There are no identified uses in cosmetic, veterinary, agricultural, or industrial applications.

Australian regulations

- According to the TGA Ingredient Database, pseudoephedrine is available for use as an active ingredient in: Biologicals, Export Only, Over the Counter and Prescription Medicines.
- As of 14 May 2026, there were 85 medicines currently active on the Australian Register of Therapeutic Goods (ARTG) that contain pseudoephedrine as an active ingredient. These include 4 prescription and 78 non-prescription medicines.
- According to the Therapeutic Goods (Permissible Ingredients) Determination No. 1 of 2026, pseudoephedrine is permitted to be included in listed medicines as follows:

Item	Ingredient name	Purpose	Specific requirements
2017	EPHEDRA DISTACHYA	A, H	Ephedrine and Pseudoephedrine (of *Ephedra distachya*) are mandatory components of *Ephedra distachya* and must be declared in the application.

[9] Therapeutic Goods Administration (2011). Scheduling delegate's final decisions – March 2011, available at web.archive.org.au/awa/20211005061524mp_///www.tga.gov.au/scheduling-decision-final/scheduling-delegates-final-decisions-march-2011; accessed 25 May 2026.

Item	Ingredient name	Purpose	Specific requirements
			The concentration of ephedrine from all ingredients in the product must be no more than 10 mg/kg or 10 mg/L or 0.001%.
2018	EPHEDRA SINICA	A, H	Ephedrine and Pseudoephedrine (of *Ephedra sinica*) are mandatory components of *Ephedra sinica*. The concentration of ephedrine from all ingredients in the product must be no more than 10 mg/kg or 10 mg/L or 0.001%.
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 H = homoeopathic preparation ingredient meaning an ingredient that is a constituent of a homoeopathic preparation			

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

Drug name	Category	Classification Level 1	Classification Level 2	Classification Level 3
Pseudoephedrine	B2	Cardiovascular System	Adrenergic stimulants	–
Pseudoephedrine	B2	Respiratory System	Decongestants	–
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 pseudoephedrine to be included on the labelling:

Substance	Conditions	Required statements
Pseudoephedrine (Entry 1 of 3)	When the preparation is NOT indicated for use for cough, cold or flu	See your doctor or pharmacist before taking pseudoephedrine if you have high blood pressure or heart problems or are taking antidepressant medication. Pseudoephedrine may cause sleeplessness if it is taken up to several hours before going to bed.
Pseudoephedrine (Entry 2 of 3)	In oral preparations indicated for cough, cold or flu which DO NOT include dosage instructions for children aged under 12 years	See your doctor or pharmacist before taking pseudoephedrine if you have high blood pressure or heart problems or are taking antidepressant medication. Pseudoephedrine may cause sleeplessness if it is taken up

Substance	Conditions	Required statements
		to several hours before going to bed. Do not give to children under 12 years of age.
Pseudoephedrine (Entry 3 of 3)	In oral preparations indicated for cough, cold or flu which include dosage instructions for children aged from 'x' years (where 'x' is 6, 7, 8, 9, 10 or 11)	See your doctor or pharmacist before taking pseudoephedrine if you have high blood pressure or heart problems or are taking antidepressant medication. Pseudoephedrine may cause sleeplessness if it is taken up to several hours before going to bed. Do not give to children under 'x' years of age. either (if 'x' is 11): Do not give to children aged 11 years, except on the advice of a doctor, pharmacist or nurse practitioner. or (if 'x' is 6, 7, 8, 9 or 10) Do not give to children aged between 'x' and 11 years of age, except on the advice of a doctor, pharmacist or nurse practitioner.

- As of 11 May 2026, in the last 10 years, there were 59 reports of adverse events for products containing pseudoephedrine as an active ingredient on the Database of Adverse Event Notifications (DAEN), with 30 reports where pseudoephedrine was the single suspected medicine. There were 8 reports of deaths associated with these reports of adverse events.
- As of 14 May 2026, there were no products containing pseudoephedrine as an active ingredient/constituent or scheduled substance listed on the Public Chemical Registration Information System Search (PubCRIS).
- Pseudoephedrine is not included by the Australian Industrial Chemicals Introduction Scheme (AICIS) on the Australian Inventory of Industrial Chemicals (Inventory).

International regulations

- The New Zealand Medsafe Medicines Classification Database lists pseudoephedrine as follows.

Substance	Conditions (if any)	Classifications
Pseudoephedrine	–	Class C3 Controlled Drug
Pseudoephedrine	Except when specified elsewhere in this schedule	Prescription
Pseudoephedrine	In solid-dose cough or decongestant medicines containing not more than 60 milligrams per	Restrict

Substance	Conditions (if any)	Classifications
	recommended dose and not more than 240 milligrams per recommended daily dose, in a pack size of 720 milligrams or less; in liquid-dose cough or decongestant medicines containing not more than 60 milligrams per recommended dose and not more than 240 milligrams per recommended daily dose, in a pack size of 800 milligrams or less	

- In New Zealand, pseudoephedrine is classified as a Class C3 controlled drug under the *Misuse of Drugs Act, 1975*, meaning it is subject to legal controls due to its moderate risk of harm, while under the *Medicines Act, 1981* it can be classified as either a prescription medicine or a restricted (pharmacist-only) medicine depending on its formulation and dosage. As of 21 May 2026, there are 11 products containing pseudoephedrine available in New Zealand as pharmacist only medicines.
- As of 21 May 2026, the US Food and Drug Administration (FDA) Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations includes 62 pseudoephedrine-containing products, of which 51 are over-the-counter and 11 are prescription medicines. These include both single-ingredient products (such as pseudoephedrine alone for nasal decongestion) and combination products (with antihistamines, analgesics, or cough suppressants) that are primarily used for the relief of cold, flu, and allergy symptoms. These products are available in multiple dosage forms, including tablets (immediate and extended-release), capsules, syrups, and oral suspensions.
- The Canadian (Health Canada) Drug Product Database includes 98 marketed products. These products are primarily non-prescription drugs, with a small number classified as narcotics (codeine-containing products). The majority are combination products containing multiple active ingredients (typically 2 to 8), although some simpler formulations contain fewer ingredients. They are available in a variety of dosage forms, including tablets, liquid capsules, softgels, syrups, oral solutions, and powders (sachets).
- In the United Kingdom, pseudoephedrine and ephedrine are classified as pharmacy (P) medicine, which are medicines that can be supplied without a prescription but only from a pharmacy under the supervision of a pharmacist. There are strict limits on the quantity that can be supplied without a prescription, with a maximum of 720 mg of pseudoephedrine allowed per transaction.[10] Pharmacy staff are also expected to monitor for signs of suspicious purchasing behaviour and may refuse a sale if misuse is suspected[i]. A search of the Medicines and Healthcare products Regulatory Agency (MHRA) database returns 319 products containing pseudoephedrine.

[10] Medicines and Healthcare products Regulatory Agency (MHRA). (2014). *Pseudoephedrine and ephedrine: nasal decongestants*. Available at https://www.gov.uk/drug-safety-update/pseudoephedrine-and-ephedrine-nasal-decongestants

2 Proposed amendments referred for scheduling advice to the Joint ACMS-ACCS meeting #44

2.1 Salicylic acid

Proposal

The Department of Health, Disability and Ageing is proposing to amend the current Poisons Standard in relation to salicylic acid. Salicylic acid for dermal use is currently classified as a Pharmacist only medicine (Schedule 3) except when containing 40% or less salicylic acid. The proposed changes intend to limit the maximum concentration of salicylic acid in unscheduled dermal preparations. The department is consulting on 2 options by either creating a Schedule 6 entry or amending the existing Schedule 3 entry as detailed below. Preparations captured under the Schedule 3 or Schedule 6 entries will also require first aid instructions (Appendix E), and warning statements and general safety directions (Appendix F) pertaining to the risk of eye exposure. The proposal is based on recommendations in the Australian Industrial Chemicals Introduction Scheme (AICIS) Evaluation statement on salicylic acid and its salts (Evaluation Statement).

Alternative name

Benzoic acid, 2-hydroxy-

CAS number

69-72-7

Proposed Scheduling

Salicylic acid is currently listed in Schedule 3 of the Poisons Standard as below.

> **Schedule 3**
>
> SALICYLIC ACID in preparations for dermal use except in preparations containing 40% or less of salicylic acid.

It is also included in Appendix H (Schedule 3 medicines permitted to be advertised) and cross-referenced to choline salicylate which is a Pharmacy medicine (Schedule 2) in preparations for oromucosal use.

Two options are being proposed to amend the scheduling of salicylic acid.

Option 1: Creation of a Poison (Schedule 6) entry for salicylic acid in dermal cosmetic preparations

Option 1 would create a Schedule 6 entry for dermal cosmetic preparations containing more than 5% salicylic acid. Such Schedule 6 preparations will also require first aid instructions (Appendix F), and warning statements and general safety directions (Appendix E) pertaining to the risk of eye exposure. The proposed amendments are as follows:[11]

> **Schedule 3 – Amend Entry**
>
> SALICYLIC ACID in preparations for dermal therapeutic use **except** in preparations containing 40% or less of salicylic acid.

[11] 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 6 – New Entry

SALICYLIC ACID in preparations for dermal cosmetic use **except** in preparations containing 5% or less of salicylic acid.

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

Item	Poison	Statement code (and statement)
308	SALICYLIC ACID and its salts in preparations for dermal cosmetic use containing more than 5% salicylic acid.	A – For advice, contact a Poisons Information Centre (e.g. phone Australia 13 11 26; New Zealand 0800 764 766) or a doctor (at once).
		E2 – If in eyes, hold eyelids apart and flush the eye continuously with running water. Continue flushing until advised to stop by a Poisons Information Centre (e.g. phone Australia 13 11 26; New Zealand 0800 764 766) or a doctor, or for at least 15 minutes.
		G3 – If swallowed, do NOT induce vomiting.

Appendix F, clause 4 – Warning statements and safety directions – New Entry

Item	Poison	Warning statement item number and statement	Safety direction item number and statement
308	SALICYLIC ACID and its salts in preparations for dermal cosmetic use containing more than 5% salicylic acid.	79 – will irritate eyes	1 – Avoid contact with eyes

Option 2: Amending the existing Schedule 3 entry to require additional warnings for exemption

This option intends to reduce the risks associated with eye exposure by requiring warning labels on dermal cosmetic preparations containing less than 5% salicylic acid to be exempt. Dermal cosmetics containing greater than 5% salicylic acid would be classified as Schedule 3 preparations. All Schedule 3 preparations will also require first aid instructions (Appendix F), and warning statements and general safety directions (Appendix E) pertaining to the risk eye exposure as in Option 1.

Schedule 3 – Amend Entry

SALICYLIC ACID in preparations for dermal use **except**:

(i) in preparations containing 40% or less of salicylic acid for dermal therapeutic use; or

(ii) in preparations containing 5% or less of salicylic acid for dermal cosmetic use when labelled with “will irritate eyes” and “avoid contact with eyes”.

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

Item	Poison	Statement code (and statement)
308	SALICYLIC ACID and its salts in preparations for dermal cosmetic use containing more than 5% salicylic acid.	A – For advice, contact a Poisons Information Centre (e.g. phone Australia 13 11 26; New Zealand 0800 764 766) or a doctor (at once).
		E2 – If in eyes, hold eyelids apart and flush the eye continuously with running water. Continue flushing until advised to stop by a Poisons Information Centre (e.g. phone Australia 13 11 26; New Zealand 0800 764 766) or a doctor, or for at least 15 minutes.
		G3 – If swallowed, do NOT induce vomiting.

Appendix F, clause 4 – Warning statements and safety directions – New Entry

Item	Poison	Warning statement item number and statement	Safety direction item number and statement
308	SALICYLIC ACID and its salts in preparations for dermal cosmetic use containing more than 5% salicylic acid.	79 – will irritate eyes	1 – Avoid contact with eye

Background

Salicylic acid is used in therapeutic products and a variety of cosmetic products including chemical peels for use by consumers at home.

Therapeutic uses of salicylic acid are mostly for dermal applications to treat skin age spots and blemishes, solar keratosis, psoriasis, warts, corns and calluses, and fungal skin infections. It is also used as a topical gel in relieving mouth ulcer pain.

The AICIS Evaluation Statement reported that, based on international use information, salicylic acid and its salts have a variety of functions and industrial applications in consumer products ranging from personal care products to household cleaning and washing products, as well as a variety of commercial and site limited uses.

Summary of reasons for the proposal

Salicylic acid and its salts were evaluated by AICIS. The Evaluation Statement identified irreversible eye damage as a primary health risk associated with high concentrations of salicylic acid. Cosmetic chemical peels pose the greatest risk as they contain up to 30% salicylic acid but are currently unscheduled. Other cosmetic applications containing up to 5% salicylic acid, such as rinse-off cosmetics, also pose slight risk of eye irritation. The Evaluation Statement recommended the scheduling of salicylic acid be amended, including introduction of requirements for first aid instructions and safety directions pertaining to eye exposure for salicylic acid preparations.

The Evaluation Statement did not recommend a specific schedule or a concentration for salicylic acid in dermal cosmetic preparations with an acceptable margin of safety. However, it identified glycolic acid as posing similar toxicity risks and usage in cosmetic formulations as salicylic acid. Glycolic acid is currently captured under Schedule 6 for concentrations greater than 5% glycolic acid

(or 20% if pH is 3.5 or greater) and require first aid instructions, warning statements, and safety directions to address risk of eye damage.

Key and expected uses

Salicylic acid and its salts are used in cosmetic products as denaturant, hair and skin conditioning agent, exfoliant, preservative or biocide. They are present in a wide range of leave-on (up to 3%) and rinse-off cosmetic products (up to 5%, except peels which are up to 30%). Salicylic acid is also used in dermal therapeutic preparations for a variety of skin conditions, as well as veterinary applications as a topical antimicrobial, antipruritic and keratolytic.

No specific Australian use, import or manufacturing information has been identified for the salts. The AICIS evaluation identified a variety of functions and applications based on international data including:

- adhesive and sealant products
- arts, crafts and hobby products
- personal care products
- paint and coating products
- plastic and polymer products
- construction products
- fabric, textile and leather products
- automotive care products
- cleaning and furniture care products
- laundry and dishwashing products
- water treatment products
- intermediate in chemical manufacturing.

Australian regulations

- According to the TGA Ingredient Database, salicylic acid is available for use as an active ingredient in: Biologicals, Export Only, Listed Medicines, Over the Counter, Prescription Medicines.
- As of 21 May 2026, there were 37 medicines currently active on the Australian Register of Therapeutic Goods (ARTG) that contain salicylic acid as an active or excipient ingredient. These include 1 prescription and 31 non-prescription medicines, with 5 listed as export-only medicines. Salicylic acid is an active ingredient in 26 registered products as shown below.

Indications	Concentration	Number of products
Cosmetic for skin age spots, freckles, blemishes)	1.50%	4
Solar keratosis	5–10%	2
Dry skin, itchy/flaking scalp, psoriasis	1.6–3%	8
Loosen crust and cradle cap	6%	1
Warts, corns, or calluses	16.7–40%	8
Fungal skin infections	3%	1
Mouth ulcer temporary pain relief	1.5–2%	2

- Salicylic acid is included in the Therapeutic Goods (Permissible Ingredients) Determination No.1 of 2026 and is permitted for use as an excipient or for homeopathic preparations for use in topical medicines for dermal application. The concentration in the medicine must be no more than 40%.
- The TGA prescribing medicines in pregnancy database does not include salicylic acid. Sodium salicylate is captured under the entry for salicylic acid and is classified as follows:

Drug name	Category	Classification Level 1	Classification Level 2	Classification Level 3
Sodium salicylate	C	Musculoskeletal System	Non-steroidal anti-inflammatory drugs (NSAIDS)	–
Category C – Drugs which, owing to their pharmacological effects, have caused or may be suspected of causing, harmful effects on the human foetus or neonate without causing malformations. These effects may be reversible. Accompanying texts should be consulted for further details.				

- The safety statement for all non-steroidal anti-inflammatory (NSAIDs) agents in the pregnancy database applies to sodium salicylate, and reads:

  > Non-steroidal anti-inflammatory (NSAIDs) agents inhibit prostaglandin synthesis which may adversely affect pregnancy. Refer to the relevant texts in the Product Information of individual NSAID products for information regarding the suitability for use in pregnancy. Epidemiological studies suggest an increased risk of spontaneous abortion after use of prostaglandin synthesis inhibitors in early pregnancy. When given during the latter part of pregnancy, may cause closure of the fetal ductus arteriosus, oligohydramnios, fetal renal impairment, inhibition of platelet aggregation, and delay labour and birth. Continuous treatment with NSAIDs during the last trimester of pregnancy should only be given on sound indications. During the last few days before expected birth, agents with an inhibitory effect on prostaglandin synthesis should be avoided.

- There are no warning statements pertaining to salicylic acid or its salts in the Therapeutic Goods (Medicines Advisory Statements) Specification 2021.
- Between 21 May 2016 and 21 May 2026, there were 346 reports of adverse events for products containing salicylic acid as an active ingredient on the Database of Adverse Event Notifications (DAEN). Salicylic acid was the single suspected medicine in 107 reports. There were 29 reports of deaths associated with these reports of adverse events.
- As of 21 May 2026, there were 11 products containing salicylic acid as an active ingredient/constituent or scheduled substance listed on the Public Chemical Registration Information System Search (PubCRIS).
- In 2009-2019 the following adverse experiences were recorded for salicylic acid in the APVMA Adverse Experience Reporting Program database (AERP):
  - 1 report of deafness classified as related to animal health (2015).
  - 1 report of pain, swelling and ulceration classified as related to animal health (2014).
- Salicylic acid and its salts are included on the Australian Inventory of Industrial Chemicals.

International regulations

- No prescription medicines listed on the United States Food and Drug Administration Approved Drug Products Database (Drugs@FDA) contain salicylic acid as an active ingredient.
- Salicylic acid is pending registration as an antimicrobial pesticide according to the United States Environmental Protection Agency's (US EPA) Office of Pesticides Programs.
- The European Commission database for information on cosmetic substances and ingredients database includes salicylic acid and its salts (calcium salicylate, magnesium salicylate, mea-salicylate, sodium salicylate, potassium salicylate, tea- salicylate) with a maximum concentration in ready to use preparations of 0.5%. They also require the following warnings:

  - Salicylic acid: Not to be used in products for children under 3 years of age. Not to be used in oral products. Not to be used in applications that may lead to exposure of the end-user's lungs by inhalation.
  - Salicylic acid salts: Not to be used in products for children under 3 years of age, except for shampoos.

- Sodium salicylate is included on the European Commission Register of medicinal products as a "Nationally authorised - Veterinary use" medicine including in a 100% powder for oral solution. There are no authorised human uses for salicylic acid.
- The European Chemicals Agency (ECHA) lists salicylic acid as a hazardous substance and is restricted in cosmetic as outlined above. It is included in the Protection of Pregnant and Breastfeeding Workers Directive, Annex I+II with a classification, labelling, and packaging (CLP) requirement of 'Repr. 2' and in the Safety and Health of Workers at Work Directive as a hazardous substance with CLP classifications 'Repr. 2; Acute Tox. 4; Eye Dam. 1.'
- New Zealand Medicines and Medical Devices Safety Authority (MedSafe) restrictions on salicylic acid align with the current Poisons Standard: 'restricted' (equivalent to Pharmacist only) medicine when containing greater than 40% salicylic acid and otherwise available for general sale.
- Salicylic acid does not have an individual approval but may be used under an appropriate group standard according to the New Zealand Inventory of Chemicals (NZIoC).
- There are 16 approved products containing salicylic acid listed on the Canadian (Health Canada) Drug Product Database. All represent non-prescription drugs. Fifteen products are listed for human use, with 1 listed for veterinary use.
- Salicylic acid and its salts are not approved for use in pesticides according to the Canada's Pest Management Regulation Agency.

How to respond

Submissions must be provided by the closing date of 30 June 2026 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 delegate's interim decisions & invitations for further comment on 30 June 2026.

Therapeutic Goods Administration

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