

Consultation: Proposed amendments to the Poisons Standard – ACMS and Joint ACMS/ACCS meetings, June 2020

17 April 2020

Scheduling amendments referred to expert advisory committee

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 June 2020 meetings of the Advisory Committee on Medicines Scheduling (ACMS #31) and the Joint Advisory Committee on Medicines and Chemicals Scheduling (Joint ACMS-ACCS #25). The ACCS #28 has been cancelled.

Submissions must be received by close of business **18 May 2020**. See [How to respond](#).

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1. Proposed amendments referred for scheduling advice to ACMS #31

1.1 Oxymetazoline

CAS Number

1491-59-4

Alternative names

Phenol, 3-[(4,5-dihydro-1H-imidazol-2-yl)methyl]-6-(1,1-dimethylethyl)-2,4-dimethyl- (IUPAC)

Applicant

Private applicant

Current scheduling

Schedule 2

OXYMETAZOLINE.

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OXYMETAZOLINE

Schedule 2

Appendix F, Part 3

It is also included under the entry oxymetazoline in Appendix F, Part 3 as follows:

Substance	Warning statements
OXYMETAZOLINE in nasal preparations for topical use:	Warning statement: 29 (If congestion persists, consult your doctor or pharmacist)

Proposed scheduling

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

Schedule 2 – Amend Entry

OXYMETAZOLINE **except in nasal preparations containing 0.05% per cent or less of oxymetazoline.**

Key uses/expected use

Medicines

Reasons for the proposal put forward by the Applicant

- Nasal congestion is the sole indication for oxymetazoline nasal sprays. It is easily recognised by the consumer without assistance from a health professional and is unlikely to be confused with other diseases or conditions.
- The use of oxymetazoline is substantially safe for short term treatment and the potential for harm from inappropriate use is very small. In this case, the maximum 3 day recommended

period of use combined with explicit warnings about frequent or prolonged use combined with warnings to avoid use in young children reduce the potential for harm to a very low level. This is supported by the low number of adverse medicine reaction reports relative to sales.

- The quality use of oxymetazoline nasal sprays can be achieved by labelling, packaging, and/or provision of other information:
 - The risk of inappropriate use in young children is addressed by the label instruction not to use in children under 6 years of age and only in children from 6 to 11 years except on the advice of a health professional;
 - The risk of rebound congestion following 3 – 5 days of continuous use is addressed by prominent 'Caution' statements on product labels.
- The risk from adverse reactions including interaction with other medicines is very low, given the topical (nasal) route of administration combined with low systemic absorption.
- The likelihood of dependency or for the product to be misused, abused or illicitly used is very low given the nature of the condition being treated, the pharmacological action of the substance concerned, the use of a topical (nasal) dose form and clear label statements limiting the duration of use to 3 days without healthcare professional advice and advising of the risk of rebound congestion.
- The choice of whether to buy or not buy the product can be made independently by the consumer without support from a pharmacist. The label advises consumers to consult a doctor or pharmacist if congestion persists.
- Nasal sprays containing phenylephrine have been available for general sale (unscheduled) since 1969. Oxymetazoline has similar pharmacodynamic and pharmacokinetic properties to phenylephrine and possibly a lower propensity for causing rebound congestion. Oxymetazoline nasal sprays are unscheduled in New Zealand.
- There are no special precautions required in handling nasal sprays containing oxymetazoline.
- Providing the public with wider access to oxymetazoline nasal sprays has the potential to improve the self-management of nasal congestion safely and effectively without the need to visit a pharmacy, thereby reducing the burden on healthcare professionals and improving health-related quality of life.
- The use of oxymetazoline falls outside the criteria for Schedules 2, 3, 4 or 8 of the Poisons Standard.

Australian regulations

- According to the [TGA Ingredient Database](https://www.ebs.tga.gov.au/),¹ oxymetazoline is:
 - Available for use as an active ingredient in biologicals, export only, over the counter and prescription medicines
 - Available for use as an excipient ingredient in biologicals, devices and prescription medicines
 - Not available as an equivalent ingredient in any application

¹ TGA Ingredient Database <https://www.ebs.tga.gov.au/>

- There are thirty (30) medicines currently active on the [Australian Register of Therapeutic Goods \(ARTG\)](#)² that contain oxymetazoline as an active ingredient. These include twenty-eight (28) non-prescription medicines and two (2) export only medicines. The formulations include nasal sprays containing 0.5 mg/mL and paediatric nasal sprays containing 0.25 mg/mL.
- Oxymetazoline is not permitted to be included in listed medicines as it is not included in the [Therapeutic Goods \(Permissible Ingredients\) Determination](#)³ No.1 of 2020.
- Oxymetazoline is not listed on the [TGA prescribing medicines in pregnancy database](#).⁴
- The [Therapeutic Goods \(Medicines Advisory Statements\) Specification 2019](#)⁵ requires the following warning statements pertaining to oxymetazoline to be included on the labelling:

Substance	Conditions	Required Statement(s)
Oxymetazoline (Entry 1 of 4)	In nasal decongestant preparations for topical use	<ul style="list-style-type: none"> • If congestion persists, consult your doctor or pharmacist. • Do not use for more than three days at a time unless advised by a doctor or pharmacist. • Frequent or prolonged use may cause nasal congestion to recur or worsen.
Oxymetazoline (Entry 2 of 4) <i>(See also vasoconstrictor eye drops)</i>	In topical eye preparations	<ul style="list-style-type: none"> • Prolonged use may be harmful. • Consult a doctor or pharmacist if using other eye products. • Do not use if you have glaucoma or other serious eye conditions. • If symptoms persist, consult a doctor or pharmacist.
Oxymetazoline (Entry 3 of 4)	In nasal decongestant preparations for topical use indicated for cough, cold or flu which DO NOT include dosage instructions for children aged under 12 years	<ul style="list-style-type: none"> • If congestion persists, consult your doctor or pharmacist. • Do not use for more than three days at a time unless advised by a doctor or pharmacist. • Frequent or prolonged use may cause nasal congestion to recur or worsen. • Do not give to children under 12 years of age.
Oxymetazoline (Entry 4 of 4)	In nasal decongestant preparations for topical use indicated for cough, cold or flu	<ul style="list-style-type: none"> • If congestion persists, consult your doctor or pharmacist. • Do not use for more than three days at a time unless advised by a doctor or pharmacist.

² ARTG database <https://www.tga.gov.au/artg>

³ Therapeutic Goods (Permissible Ingredients) Determination

[https://www.legislation.gov.au/Search/Therapeutic%20Goods%20LB\\$Permissible%20Ingredients\\$RB\\$%20Determination](https://www.legislation.gov.au/Search/Therapeutic%20Goods%20LB$Permissible%20IngredientsRB%20Determination)

⁴ TGA prescribing medicines in pregnancy database <https://www.tga.gov.au/prescribing-medicines-pregnancy-database>

⁵ Therapeutic Goods (Medicines Advisory Statements) Specification 2019 <https://www.legislation.gov.au/Details/F2019L00213>

Substance	Conditions	Required Statement(s)
	which include dosage instructions for children aged from 'x' to 11 years (where 'x' is 6, 7, 8, 9, 10 or 11)	<ul style="list-style-type: none"> • Frequent or prolonged use may cause nasal congestion to recur or worsen. • Do not give to children under 'x' years of age. • <i>either (if 'x' is 11)</i> <ul style="list-style-type: none"> - Do not give to children aged 11 years, except on the advice of a doctor, pharmacist or nurse practitioner. • <i>or (if 'x' is 6, 7, 8, 9 or 10)</i> <ul style="list-style-type: none"> - Do not give to children aged between 'x' and 11 years of age, except on the advice of a doctor, pharmacist or nurse practitioner.
Vasoconstrictor eye drops including: <ul style="list-style-type: none"> • Naphazoline • Oxymetazoline • Phenylephrine • Tetrahydrozoline • Tramazoline • Tymazoline • Xylometazoline 	In topical eye preparations	<ul style="list-style-type: none"> • Prolonged use may be harmful. • Consult a doctor or pharmacist if using other eye products. • Do not use if you have glaucoma or other serious eye conditions. • If symptoms persist, consult a doctor or pharmacist.

- From 01/01/1971 – 16/12/2019, the [Database of Adverse Event Notifications \(DAEN\)](#)⁶ contains 136 reports of adverse events for products containing oxymetazoline as an active ingredient, with 122 reports where oxymetazoline was the single suspected medicine. There were one report of death associated with oxymetazoline use.
- There are no products containing oxymetazoline listed on the [Public Chemical Registration Information System Search \(PubCRIS\)](#).⁷

⁶ Database of Adverse Event Notifications (DAEN) <https://apps.tga.gov.au/Prod/daen/daen-entry.aspx>

⁷ Public Chemical Registration Information System Search (PubCRIS) <https://portal.apvma.gov.au/pubcris>

International regulations

- According to Medsafe New Zealand, oxymetazoline is classified as follows:

Ingredient	Conditions	Classification
Oxymetazoline	<ul style="list-style-type: none">• except for nasal use when sold at an airport;• except for ophthalmic use when sold in practice by an optometrist registered with the Optometrists and Dispensing Opticians Board;• except for nasal use in medicines containing 0.05% or less when sold in the manufacturer's original pack with a pack size of 20 millilitres or less	Pharmacy Only
Oxymetazoline	<ul style="list-style-type: none">• for nasal use when sold at an airport;• for ophthalmic use when sold in practice by an optometrist registered with the Optometrists and Dispensing Opticians Board;• for nasal use in medicines containing 0.05% or less when sold in the manufacturer's original pack with a pack size of 20 millilitres or less	General Sale

- In Canada, oxymetazoline is available in over the counter medicines, in preparations containing 0.025 to 0.05% oxymetazoline.
- In the United States, oxymetazoline is available in over the counter and prescription medicines. Over the counter preparation are available at a concentration of 0.025%. Prescription medicine preparations include a 1% cream for the topical treatment of erythema associated with rosacea.
- In the United Kingdom (UK), oxymetazoline is included on the General Sales List (GSL)⁸ and is available in nasal sprays at a concentration of 0.05%. Medicines on the GSL can be sold or supplied otherwise than by or under the supervision of a pharmacist.
- In the European Union (EU) oxymetazoline is approved for use in over the counter nasal decongestants.

⁸ <https://www.nhs.uk/common-health-questions/medicines/what-is-the-law-on-the-sale-of-medicines/>

1.2 Eletriptan

CAS Number

143322-58-1 (eletriptan)

177834-92-3 (eletriptan hydrobromide)

Alternative names

(R)-3-(1-methyl-2-pyrrolidinylmethyl)-5-[2-(phenylsulfonyl)ethyl]-1H-indole hydrobromide

Applicant

Private applicant

Current scheduling

Schedule 4

ELETRIPTAN.

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ELETRIPTAN

Proposed scheduling

Schedule 4 – Amend entry

ELETRIPTAN **except when included in Schedule 3.**

Schedule 3 – New Entry

ELETRIPTAN for oral use in tablets containing 40 mg or less per tablet and when in a pack containing not more than 2 dosage units.

Appendix H – New Entry

ELETRIPTAN

Index – Amend Entry

ELETRIPTAN

Schedule 4

Schedule 3

Appendix H

Key uses/expected use

Medicines

Reasons for the proposal put forward by the Applicant

- Sumatriptan and zolmitriptan have both received positive [interim decisions](#) for re-scheduling to Schedule 3, with a proposed implementation date of 1 February 2021.
- The safety profile of eletriptan is comparable to sumatriptan and zolmitriptan. The risks associated with eletriptan are not molecule specific but rather therapeutic class associated i.e. “Triptans” or 5HT1 agonists.

- Eletriptan meets the requirements of all Schedule 3 Scheduling Factors.

Australian regulations

- According to the [TGA Ingredient Database](#),⁹ eletriptan is available for use as an:
 - Active ingredient in biologicals and prescription medicines
 - Excipient ingredient in biologicals, devices and prescription medicines
 - Equivalent ingredient in prescription medicines
- According to the [TGA Ingredient Database](#),¹⁰ eletriptan hydrobromide is:
 - Available for use as an active ingredient in biologicals, export only and prescription medicines
 - Available for use as an excipient ingredient in biologicals, devices and prescription medicines
 - Not available as an Equivalent Ingredient in any application
- According to the [TGA Ingredient Database](#),¹¹ eletriptan hydrobromide monohydrate is:
 - Available for use as an active ingredient in export only and prescription medicines
 - Not available as an excipient ingredient in any application
 - Available for use as an equivalent ingredient in export only and prescription medicines
- There are 20 prescription medicines currently active on the [Australian Register of Therapeutic Goods \(ARTG\)](#)¹² that contain eletriptan as an active ingredient. These include 20 prescription medicines in tablet formulations.
- Eletriptan is not permitted to be included in listed medicines as it is not included in the [Therapeutic Goods \(Permissible Ingredients\) Determination](#)¹³ No.1 of 2020.
- The [TGA prescribing medicines in pregnancy database](#)¹⁴ classifies eletriptan as:

Drug name	Category	Classification Level 1	Classification Level 2	Classification Level 3
Eletriptan	B1	Cardiovascular System	Antimigraine preparations	-
<p>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.</p> <p>Studies in animals have not shown evidence of an increased occurrence of foetal damage.</p>				

⁹ TGA Ingredient Database <https://www.ebs.tga.gov.au/>

¹⁰ TGA Ingredient Database <https://www.ebs.tga.gov.au/>

¹¹ TGA Ingredient Database <https://www.ebs.tga.gov.au/>

¹² ARTG database <https://www.tga.gov.au/artg>

¹³ Therapeutic Goods (Permissible Ingredients) Determination

[https://www.legislation.gov.au/Search/Therapeutic%20Goods%20LB\\$Permissible%20Ingredients\\$RB\\$%20Determination](https://www.legislation.gov.au/Search/Therapeutic%20Goods%20LB$Permissible%20IngredientsRB%20Determination)

¹⁴ TGA prescribing medicines in pregnancy database <https://www.tga.gov.au/prescribing-medicines-pregnancy-database>

- There are no warning statements pertaining to eletriptan in the [Therapeutic Goods \(Medicines Advisory Statements\) Specification 2019](#)¹⁵ as eletriptan is a Prescription Only Medicine and RAMSL is not applicable.
- Between 01/01/1971 - 17/12/2019, the [Database of Adverse Event Notifications \(DAEN\)](#)¹⁶ contains 26 reports of adverse events for products containing eletriptan as an active ingredient, with 22 reports where eletriptan was the single suspected medicine. There are no reports of deaths associated with eletriptan use. The top three reported reactions include chest discomfort, nausea and overdose.
- There are no products containing eletriptan listed on the [Public Chemical Registration Information System Search \(PubCRIS\)](#).¹⁷

International regulations

- Eletriptan is currently registered in 91 countries and is marketed in over 50 countries for the treatment of migraine.
- In the United States (US), Canada, United Kingdom (UK), European Union (EU) and New Zealand, eletriptan is classified as a prescription medicine.

1.3 Clotrimazole

CAS Number

23593-75-1

Alternative names

1-[(2-chlorophenyl)-diphenylmethyl]imidazole (IUPAC)

Applicant

Private applicant

Current scheduling

Schedule 6

CLOTRIMAZOLE for the external treatment of animals.

Schedule 4

CLOTRIMAZOLE except:

- a) when included in Schedule 2, 3 or 6; or
- b) in preparations for dermal use for the treatment of tinea pedis.

Schedule 3 – Amend Entry

CLOTRIMAZOLE in preparations for vaginal use.

¹⁵ Therapeutic Goods (Medicines Advisory Statements) Specification 2019 <https://www.legislation.gov.au/Details/F2019L00213>

¹⁶ Database of Adverse Event Notifications (DAEN) <https://apps.tga.gov.au/Prod/daen/daen-entry.aspx>

¹⁷ Public Chemical Registration Information System Search (PubCRIS) <https://portal.apvma.gov.au/pubcris>

Schedule 2 – Amend Entry

CLOTRIMAZOLE for human use in dermal preparations and for application to the nails **except** in preparations for the treatment of tinea pedis.

Appendix F, Part 3

Poison	Warning statements	Safety directions
CLOTRIMAZOLE in vaginal preparations when included in Schedule 3.	54,63,64,66	

Appendix H

CLOTRIMAZOLE

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CLOTRIMAZOLE

Schedule 6

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Proposed scheduling

Schedule 3 – Amend Entry

CLOTRIMAZOLE in preparations for vaginal use **except when included in Schedule 2.**

Schedule 2 – Amend Entry

CLOTRIMAZOLE for human use:

- a) in preparations for vaginal use containing 1 per cent or less of clotrimazole; or
- b) in dermal preparations; and
- c) for application to the nails.

except in preparations for the treatment of tinea pedis.

Appendix F, Part 3

Poison	Warning statements	Safety directions
CLOTRIMAZOLE in vaginal preparations when included in Schedule 2 or Schedule 3.	54,63,64,66	

Key uses/expected use

Medicines

Reasons for the proposal put forward by the Applicant

- The applicant proposes to make clotrimazole 1% vaginal cream directly available to consumers from pharmacies without the need to consult a pharmacist or doctor.
- Vaginal candidiasis is a common occurrence with 12.5% of Australian women experiencing at least one episode in the last 12 months. Of these women:
 - 82% were repeat sufferers;
 - 76% were confident of their ability to self-diagnose and treat thrush;
 - 70% were uncomfortable about speaking with a pharmacist about thrush, 70% wanted the option to self-select and only 2% preferred to speak with a pharmacist rather than self-selecting;
 - the 42% of participants who had not treated their thrush reported finding it 'very uncomfortable' to speak with a pharmacist;
 - 30% of those who believed asking for help is 'very embarrassing' purchased the XXXXX regular antifungal cream inappropriately for vaginal use.
- XXXXX vaginal creams are a safe and effective first-line treatment for vulvovaginal candidiasis. They have low potential toxicity and a low potential for abuse.
- Products are clearly labelled to provide all the information that is needed to ensure the quality use of the medicine including an instruction to consult a health care professional "if you have not had thrush before".
- A 2005 Australian study (Tenni 2005) found a self-diagnostic accuracy rate for vaginal candidiasis of 47% with a further 42% having 'normal' vaginal flora. The combined 'do no harm' scenario for these consumers (i.e. successful treatment + no treatment required) was 89%.
- Women who have had vaginal candidiasis previously diagnosed by a doctor will already be familiar with the symptoms. Other vaginal infections will usually have different symptoms as described on the pack with a prompt to seek healthcare professional advice if no improvement in 4 days.
- This application is limited to the lowest strength clotrimazole 1% (6 day) vaginal cream. No change is proposed to the current Schedule 3 entries covering pessaries and the 3 day 2% and 1 day 10% creams.
- The proposed SUSMP entry for clotrimazole 1% vaginal cream meets all of the SPF criteria for Schedule 2.

Australian regulations

As of March 2020:

- There are 94 medicines currently active on the [Australian Register of Therapeutic Goods \(ARTG\)](https://www.tga.gov.au/artg)¹⁸ that list clotrimazole as an active ingredient. These include 1 prescription, 92 non-prescription medicines and 1 export-only medicine. Clotrimazole is available in the following formulations types: cream, capsules, topical solution and pessaries.

¹⁸ ARTG database <https://www.tga.gov.au/artg>

- According to the [TGA Ingredient Database](#),¹⁹ clotrimazole is:
 - available for use as an active ingredient in biologicals, export only, over the counter and prescription medicines;
 - available for use as an excipient ingredient in biologicals, devices, prescription medicines; and
 - not available as an equivalent ingredient in any application.
- Clotrimazole is not permitted to be included in listed medicines as it is not included in the [Therapeutic Goods \(Permissible Ingredients\) Determination](#)²⁰ No.1 of 2020.
- The [TGA prescribing medicines in pregnancy database](#)²¹ classifies clotrimazole as:

Drug name	Category	Classification Level 1	Classification Level 2	Classification Level 3
Clotrimazole	A	Drugs used in Dermatology	Topical antifungals, antiseptics (see also antifungal agents)	
Clotrimazole	A	Genitourinary System	Topical vaginal medication	

Category A – Drugs which have been taken by a large number of pregnant women and women of childbearing age without any proven increase in the frequency of malformations or other direct or indirect harmful effects on the foetus having been observed.

- The [Therapeutic Goods \(Medicines Advisory Statements\) Specification 2019](#)²² requires the following warning statements pertaining to clotrimazole to be included on the labelling:

Substance	Conditions	Required Statement(s)
Clotrimazole	In preparations for vaginal use	<ul style="list-style-type: none"> • Seek medical advice before first course of treatment. • See a doctor if you are pregnant or diabetic. • See a doctor if no better after [<i>Insert number of days as per approved Product Information</i>] days. • See a doctor if problem returns.

- The [Database of Adverse Event Notifications \(DAEN\)](#)²³ contains 176 reports of adverse events for products containing clotrimazole as an active ingredient, with 128 reports where

¹⁹ TGA Ingredient Database <https://www.ebs.tga.gov.au/>

²⁰ Therapeutic Goods (Permissible Ingredients) Determination [https://www.legislation.gov.au/Search/Therapeutic%20Goods%20LB\\$Permissible%20Ingredients\\$RB%20Determination](https://www.legislation.gov.au/Search/Therapeutic%20Goods%20LB$Permissible%20Ingredients$RB%20Determination)

²¹ TGA prescribing medicines in pregnancy database <https://www.tga.gov.au/prescribing-medicines-pregnancy-database>

²² Therapeutic Goods (Medicines Advisory Statements) Specification 2019 <https://www.legislation.gov.au/Details/F2019L00213>

²³ Database of Adverse Event Notifications (DAEN) <https://apps.tga.gov.au/Prod/daen/daen-entry.aspx>

clotrimazole was the single suspected medicine. There was 1 report of death associated with clotrimazole use.

- There are five products containing clotrimazole listed on the [Public Chemical Registration Information System Search \(PubCRIS\)](#).²⁴ These include two approved active constituents and three registered products.
- In 2009-2019 the following adverse experiences were recorded for clotrimazole in the [APVMA Adverse Experience Reporting Program database \(AERP\)](#):²⁵
 - Five reports, with two reports where clotrimazole was the probable cause and three reports where clotrimazole was a possible cause (2009);
 - Three reports, with two reports where clotrimazole was the probable cause and one report where clotrimazole was a possible cause (2010);
 - Three reports where clotrimazole was a possible cause (2012);
 - One report where clotrimazole was the probable cause (2013);
 - Three reports, with one report where clotrimazole was the probable cause and two reports where clotrimazole was a possible cause (2014);
 - One report on clotrimazole related to crop health (2015);
 - One report on clotrimazole related to animal health (2016); and
 - One report on clotrimazole related to animal health (2017).

International regulations

As of March 2020 the following international regulatory information was available for clotrimazole:

United States (U.S)

According to the [United States Food and Drug Administration Approved Drug Products Database \(Drugs@FDA\)](#)²⁶ clotrimazole is available as a prescription and over-the-counter medicine in the U.S. Clotrimazole is not identified on the [United States Environmental Protection Agency's \(US EPA\) Office of Pesticides Programs](#).²⁷

Europe

The [European Chemicals Agency \(ECHA\)](#)²⁸ hazard classification & labelling classifies for clotrimazole is '*Danger! According to the classification provided by companies to ECHA in CLP notifications this substance is very toxic to aquatic life with long lasting effects, is very toxic to aquatic life, is toxic in contact with skin, is harmful if swallowed, causes serious eye irritation, is suspected of damaging fertility or the unborn child, may cause damage to organs through prolonged or repeated exposure and causes skin irritation.*' Clotrimazole is predicted as likely to meet criteria for category 1A or 1B carcinogenicity, mutagenicity, or reproductive toxicity according to ECHA.

²⁴ Public Chemical Registration Information System Search (PubCRIS) <https://portal.apvma.gov.au/pubcris>

²⁵ APVMA Adverse Experience Reporting Program [database \(AERP\) https://apvma.gov.au/node/10946](https://apvma.gov.au/node/10946)

²⁶ FDA Approved Drug Products Database <https://www.accessdata.fda.gov/scripts/cder/daf/>

²⁷ United States Environmental Protection Agency's (US EPA) Office of Pesticides Programs <https://iaspub.epa.gov/apex/pesticides/f?p=CHEMICALSEARCH:1>

²⁸ European Chemicals Agency (ECHA) <https://echa.europa.eu/search-for-chemicals>

The [European Commission database for information on cosmetic substances and ingredients database](#)²⁹ identifies clotrimazole as an ingredient in anti-dandruff and anti-microbial products. Clotrimazole is not included on the [European Union Pesticides Database](#).³⁰ According to the [European Medicines Agency](#),³¹ clotrimazole is available in a number of products with current market approval.

New Zealand (NZ)

Clotrimazole was first included in the [New Zealand Inventory of Chemicals \(NZIoC\)](#)³² on 1 December 2006. According to the [New Zealand Medicines and Medical Devices Safety Authority \(MedSafe\)](#)³³ clotrimazole is available as follows in NZ:

Ingredient	Conditions (if any)	Classification
Clotrimazole	except in medicines for vaginal or external use	Prescription
Clotrimazole	for vaginal use	Restricted
Clotrimazole	for external use except in medicines for tinea pedis only or when sold in practice by a podiatrist registered with the Podiatrists Board	Pharmacy Only
Clotrimazole	for external use in medicines for tinea pedis only or when sold in practice by a podiatrist registered with the Podiatrists Board	General Sale

Canada

Clotrimazole is not included in [Canada's Pest Management Regulation Agency](#).³⁴ According to the [Canadian \(Health Canada\) Drug Product Database](#)³⁵ clotrimazole is available as a prescription medicine and over-the-counter medicine in Canada.

1.4 Sildenafil

CAS Number

139755-83-2

Alternative names

5-[2-Ethoxy-5-[(4-methylpiperazin-1-yl)sulfonyl]phenyl]-1-methyl-3-propyl-1,6-dihydro-7H-pyrazolo[4,3-d]pyrimidin-7-one dihydrogen 2-hydroxypropane-1,2,3- tricarboxylate

²⁹ [European Commission database for information on cosmetic substances and ingredients database](https://ec.europa.eu/growth/tools-databases/cosing/)
<https://ec.europa.eu/growth/tools-databases/cosing/>

³⁰ [European Union Pesticides Database](https://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/public/?event=activesubstance.selection&language=EN)
<https://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/public/?event=activesubstance.selection&language=EN>

³¹ [European Medicines Agency](https://www.ema.europa.eu/en/medicines)
<https://www.ema.europa.eu/en/medicines>

³² [New Zealand Inventory of Chemicals \(NZIoC\)](https://www.epa.govt.nz/database-search/new-zealand-inventory-of-chemicals-nzioc/DatabaseSearchForm/?SiteDatabaseSearchFilters=36&Keyword=acequinocyl&DatabaseType=NZIOC)
<https://www.epa.govt.nz/database-search/new-zealand-inventory-of-chemicals-nzioc/DatabaseSearchForm/?SiteDatabaseSearchFilters=36&Keyword=acequinocyl&DatabaseType=NZIOC>

³³ [New Zealand Medicines and Medical Devices Safety Authority \(MedSafe\)](https://www.medsafe.govt.nz/profs/class/classintro.asp)
<https://www.medsafe.govt.nz/profs/class/classintro.asp>

³⁴ [Canada's Pest Management Regulation Agency](https://pesticide-registry.canada.ca/en/active-ingredient-search.html)
<https://pesticide-registry.canada.ca/en/active-ingredient-search.html>

³⁵ [Canadian \(Health Canada\) Drug Product Database](https://health-products.canada.ca/dpd-bdpp/index-eng.jsp)
<https://health-products.canada.ca/dpd-bdpp/index-eng.jsp>

Applicant

Private applicant

Current scheduling

Schedule 4

SILDENAFIL.

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SILDENAFIL

Schedule 4

Proposed scheduling

Schedule 4 – Amend Entry

SILDENAFIL **except** when included in Schedule 3.

Schedule 3 – New Entry

SILDENAFIL in divided preparations for oral use containing 50 mg of sildenafil per dosage unit in packs of not more than 4 dosage units in accordance with the requirements of Appendix M.

Appendix M – New Entry

Appendix M

SILDENAFIL where the pharmacist providing professional advice:

- Has demonstrated achievement of competency through completion of an accredited training course that meets the requirements set out in the Pharmaceutical Society of Australia competency-based education framework for supply of sildenafil as a Pharmacist Only medicine; and
- Complies in all respects with the relevant professional practice standards, and the Pharmaceutical Society of Australia professional practice guidance for supply of sildenafil as a Pharmacist Only medicine; and
- Confirms a PDE5 inhibitor has previously been prescribed by a medical practitioner for the patient for treatment of erectile dysfunction; and
- Documents the supply of sildenafil in a clinical information system in accordance with professional practice guidance.

Appendix H – New Entry

SILDENAFIL.

Index – Amend Entry

SILDENAFIL

Schedule 4

Schedule 3

Appendix H

Appendix M

Key uses/expected use

Medicines

Reasons for the proposal put forward by the Applicant

- The proposed changes meet all of the criteria for Appendix M and Appendix H and the factors for Schedule 3 in relation to the supply of sildenafil.
- The availability of sildenafil in pharmacy after initial prescribing by a medical practitioner will be of particular benefit to men without ready access to medical facilities (e.g. shift workers or people in rural or remote areas). Pharmacies are well distributed in urban and rural areas throughout Australia with wider, more flexible operating hours than physician practices. They offer direct and convenient access to professional health care and treatment advice.
- Increased awareness of erectile dysfunction (ED) through advertising, and availability of treatment through consultation with a suitably-trained pharmacist will encourage men to discuss the available treatment options with their pharmacist and / or medical practitioner.
- Advertising will encourage men with ED to seek early engagement with the health care system via a suitably-trained pharmacist. Compliance with the Appendix M criteria will ensure that these men are properly assessed and counselled by the pharmacist before supply of sildenafil, or not supplied sildenafil and referred to a medical practitioner.
- Under the proposed Appendix M conditions sildenafil is substantially safe with pharmacist intervention to ensure the quality use of this medicine.

Australian regulations

- According to the [TGA Ingredient Database](#):³⁶
 - sildenafil is available as an:
 - § active ingredient in biologicals, export, and prescription medicines;
 - § excipient ingredient in biologicals, devices and prescription medicines; and
 - § equivalent ingredient in prescription medicines
 - Sildenafil citrate is available as an:
 - § Active ingredient in biologicals, export only, over the counter and prescription medicines;
 - § Excipient ingredient in biologicals, devices and prescription medicines; and
 - § is not available as an equivalent ingredient in any application
- There are 112 medicines currently active on the [Australian Register of Therapeutic Goods \(ARTG\)](#)³⁷ that contain sildenafil as an active ingredient. All 112 are prescription medicines with one of the following formulations: tablet, capsule, sublingual wafer or injectable solution.

³⁶ TGA Ingredient Database <https://www.ebs.tga.gov.au/>

³⁷ ARTG database <https://www.tga.gov.au/artg>

- Sildenafil is not permitted to be included in listed medicines as it is not included in the [Therapeutic Goods \(Permissible Ingredients\) Determination](#)³⁸ No.1 of 2020.
- The [TGA prescribing medicines in pregnancy database](#)³⁹ classifies sildenafil as:

Drug name	Category	Classification Level 1	Classification Level 2	Classification Level 3
Sildenafil citrate	B1	Cardiovascular System	Vasodilators	
<p>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.</p> <p>Studies in animals have not shown evidence of an increased occurrence of foetal damage.np</p>				

- There are no warning statements pertaining to sildenafil in the [Therapeutic Goods \(Medicines Advisory Statements\) Specification 2019](#)⁴⁰
- The [Database of Adverse Event Notifications \(DAEN\)](#)⁴¹ contains 1211 reports of adverse events for products containing sildenafil as an active ingredient, with 989 reports where sildenafil was the single suspected medicine. There were 81 reports of deaths associated with sildenafil use.
- There are no products containing sildenafil listed on the [Public Chemical Registration Information System Search \(PubCRIS\)](#).⁴²

International regulations

- The [United States Food and Drug Administration Approved Drugs Database \(Drugs@FDA\)](#)⁴³ includes sildenafil citrate as a prescription medicine in oral tablet (20 mg, 25 mg, 50 mg and 100 mg) and oral suspension (10 mg/mL) forms and as an intravenous solution (8 mg/mL).
- According to the [Health Canada Drug Product Database](#),⁴⁴ sildenafil citrate is available as a prescription medicine in oral tablet form (25 mg, 50 mg, 100 mg).
- In November 2017, the [UK Medicines and Healthcare products Regulatory Agency](#)⁴⁵ (MHRA) formally classified sildenafil 50 mg from a prescription only medicine (POM) to a pharmacy medicine (P). Sildenafil 50 mg could be available without prescription for use by men over 18 who have ED. This decision was made following an assessment of the safety of XXXX advice from the Commission on Human Medicines and a public consultation with positive outcome. Sildenafil 50 mg is sold in pharmacies following a discussion with the pharmacist. Pharmacists determine whether treatment is appropriate for the patient and can give advice

³⁸ Therapeutic Goods (Permissible Ingredients) Determination

[https://www.legislation.gov.au/Search/Therapeutic%20Goods%20\\$LB\\$Permissible%20Ingredients\\$RB\\$%20Determination](https://www.legislation.gov.au/Search/Therapeutic%20Goods%20LBPermissible%20IngredientsRB%20Determination)

³⁹ TGA prescribing medicines in pregnancy database <https://www.tga.gov.au/prescribing-medicines-pregnancy-database>

⁴⁰ Therapeutic Goods (Medicines Advisory Statements) Specification 2019 <https://www.legislation.gov.au/Details/F2019L00213>

⁴¹ Database of Adverse Event Notifications (DAEN) <https://apps.tga.gov.au/Prod/daen/daen-entry.aspx>

⁴² Public Chemical Registration Information System Search (PubCRIS) <https://portal.apvma.gov.au/pubcris>

⁴³ FDA Approved Drug Products Database <https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=BasicSearch.process>

⁴⁴ Health Canada Drug Product Database <https://health-products.canada.ca/dpd-bdpp/index-eng.jsp>

⁴⁵ UK MHRA

[https://www.evidence.nhs.uk/search?cid=5551&fc=Off&om=\[%7B%22srn%22:%22Medicines%20and%20Healthcare%20products%20Regulatory%20Agency%20-%20MHRA%22\]%7D\]&q=capecitabine&sp=on](https://www.evidence.nhs.uk/search?cid=5551&fc=Off&om=[%7B%22srn%22:%22Medicines%20and%20Healthcare%20products%20Regulatory%20Agency%20-%20MHRA%22]%7D]&q=capecitabine&sp=on)

on ED, usage of the medicine, potential side effects and if further consultation with a general practitioner is required.

XXXX will not be sold to those with severe cardiovascular disease (CVD); at high cardiovascular risk; liver failure; severe kidney failure; or taking certain interacting medicines. Use of XXXX in these groups of men must continue to be under the supervision of a doctor.

- The [New Zealand Medicines and Medical Devices Safety Authority \(MedSafe\)](#),⁴⁶ classifies sildenafil as follows:

Ingredient	Conditions	Classification
Sildenafil and its structural analogues	except sildenafil in medicines for oral use containing 100 milligrams or less per dose unit when sold in the manufacturer's original pack containing not more than 12 solid dosage units for the treatment of erectile dysfunction in males aged 35-70 years by a registered pharmacist who has successfully completed a training programme endorsed by the Pharmaceutical Society of New Zealand	Prescription

1.5 Ibuprofen

CAS Number

15687-27-1

Alternative names

2-[4-(2-methylpropyl)phenyl]propanoic acid

Applicant

Private applicant

Current scheduling

Schedule 4

IBUPROFEN **except:**

- a) when included in or expressly excluded from Schedule 2 or 3; or
- b) in preparations for dermal use.

Schedule 3

IBUPROFEN:

- a) in divided preparations, each containing 400 mg or less of ibuprofen in a primary pack containing not more than 50 dosage units, when labelled:
 - i) with a recommended daily dose of 1200 mg or less of ibuprofen; and

⁴⁶ New Zealand Medicines and Medical Devices Safety Authority (MedSafe) <https://www.medsafe.govt.nz/profs/class/classintro.asp>

- ii) not for the treatment of children under 12 years of age; or
- b) in a modified release dosage form, each containing 600 mg of ibuprofen in a primary pack containing not more than 32 dosage units, when labelled:
 - i) with a recommended daily dose of 1200 mg or less of ibuprofen; and
 - ii) not for the treatment of children under 12 years of age;**except** when included in or expressly excluded from Schedule 2.

Schedule 2

IBUPROFEN in preparations for oral use when labelled with a recommended daily dose of 1200 mg or less of ibuprofen:

- a) in liquid preparations when sold in the manufacturer's original pack containing 8 g or less of ibuprofen; or
- b) in divided preparations, each containing 200 mg or less of ibuprofen, in packs of not more than 100 dosage units **except** when:
 - i) as the only therapeutically active constituent (other than phenylephrine or when combined with an effervescent agent);
 - ii) packed in blister or strip packaging or in a container with a child-resistant closure;
 - iii) in a primary pack containing not more than 25 dosage units;
 - iv) compliant with the requirements of the Required Advisory Statements for Medicine Labels;
 - v) not labelled for the treatment of children 6 years of age or less; and
 - vi) not labelled for the treatment of children under 12 years of age when combined with phenylephrine.

IBUPROFEN

cross reference: PARACETAMOL

Schedule 4

Schedule 3

Schedule 2

Appendix F, Part 3

Appendix H

Proposed scheduling

Schedule 2 – Amend Entry

IBUPROFEN in preparations for oral use when labelled with a recommended daily dose of 1200 mg or less of ibuprofen:

- a) in liquid preparations when sold in the manufacturer's original pack containing 8 g or less of ibuprofen; or
- b) in divided preparations, each containing 200 mg or less of ibuprofen, in packs of not more than 100 dosage units **except** when:
 - i) as the only therapeutically active constituent (other than phenylephrine or when combined with an effervescent agent);
 - ii) packed in blister or strip packaging or in a container with a child-resistant closure;

- iii) in a primary pack containing not more than 25 dosage units;
 - iv) compliant with the requirements of the Required Advisory Statements for Medicine Labels;
 - v) not labelled for the treatment of children 6 years of age or less; and
 - vi) not labelled for the treatment of children under 12 years of age when combined with phenylephrine.
- c) in divided preparations, each containing 400 mg or less of ibuprofen in a primary pack containing not more than 12 dosage units, when labelled:
- i) not for the treatment of children under 12 years of age.

Key uses/expected use

Medicines

Reasons for the proposal put forward by the Applicant

- Ibuprofen 400 mg with a maximum daily dose of 1200 mg in a primary pack containing no more than 12 dosage units is a safe and well-tolerated medication, providing short-term relief from acute pain and fever.
- The public health benefits of having a small pack (limited to no more than 12 dosage units) of ibuprofen 400 mg in Schedule 2 is broader than the convenience of and preference for taking fewer tablets.
- Since the rescheduling of all codeine based analgesics to Schedule 4 there is a need to improve availability of OTC treatments to manage strong pain. The 400 mg double strength tablets are likely to be used by people seeking relief of stronger pain. Cochrane reviews have confirmed that the 400 mg dose is more efficacious than the 200 mg dose with equivalent tolerability. In addition, a single dose of ibuprofen 400 mg has been clinically demonstrated to be as efficacious as the fixed combination of paracetamol/ibuprofen (500 mg/200 mg) (one tablet) one of the main Schedule 2 options for the relief of acute strong pain.
- Ibuprofen 400 mg is appropriate for inclusion in Schedule 2 as it has a superior risk-benefit profile to that of paracetamol, aspirin and diclofenac, as single agents, as well as paracetamol/ibuprofen combinations. Ibuprofen 400 mg is as effective as the combination analgesic and is a safer option as people are only exposed to one active ingredient that is as well tolerated as paracetamol and is safer than paracetamol in overdose situations.
- It is noted that concerns regarding paracetamol overdose in combination products (paracetamol/ibuprofen) was highlighted as a reason to maintain its current Pharmacy scheduling status at the November 2019 ACMS meeting. Consequently, improving the availability of 400 mg ibuprofen by permitting self-selection as a Schedule 2 medicine will provide consumers with an effective and safe option to relieve strong pain.
- Approximately 1 in 6 customers of Australian pharmacies have difficulty swallowing oral medications, and having the option to take one small 400 mg tablet will provide these people the benefit of taking fewer tablets to help manage their strong pain. For the vast majority, this difficulty is not due to an underlying medical condition but is due to the fact that swallowing medications whole is not a natural process. For these people the benefit of taking fewer tablets is meaningful and is not adequately addressed by the current scheduling as swallowing difficulties are not commonly discussed.
- OTC ibuprofen (doses \leq 1200 mg/day) is well tolerated and when taken as directed has a gastrointestinal safety profile equivalent to paracetamol and superior to aspirin. Ibuprofen's

safety in overdose is superior to paracetamol. The maximum daily dose for Schedule 2 400 mg ibuprofen will remain the same as regular 200 mg ibuprofen and the pack size will be limited to 4 days' supply (12 tablets), hence the Schedule 2 availability does not pose additional safety risk. In addition, a risk-benefit assessment of OTC analgesics concluded that ibuprofen (both as the acid and faster dissolving salts) had a superior risk-benefit profile than paracetamol and aspirin.

- The safety profile associated with the short-term use of ibuprofen 400 mg and 200 mg are essentially the same and are equivalent to placebo. As such the use of 400 mg ibuprofen instead of the regular 200 mg is unlikely to pose any additional safety risk.
- A review of cardiorenal safety of OTC ibuprofen demonstrated that there is little risk of cardiovascular adverse events when used as per the product label. The risk is essentially equivalent to that of placebo or no-use in people with (e.g. older people with pre-existing risk factors) and without contraindications as defined on the label. In addition, epidemiologic studies of prolonged use of OTC doses of ibuprofen overall reinforce its favourable cardiorenal safety profile.
- A systemic review of community-based controlled observational studies indicated that amongst widely used NSAIDs, low-dose ibuprofen (i.e. OTC dose) appears to be free of cardiovascular risk and is one of the NSAIDs least likely to increase cardiovascular risk.
- The TGA reviewed the cardiovascular safety of NSAIDs in 2014 and determined that while changes to the label would further clarify to consumers the need to avoid NSAIDs in patients with existing cardiovascular disease, it also determined that current scheduling remained appropriate.
 - The evidence enclosed in this submission demonstrates that ibuprofen 400 mg in primary packs limited to 12 dosage units or less is suitable for inclusion in Schedule 2.
 - The approved indications for ibuprofen 400 mg are the same as that for regular ibuprofen 200 mg which are available as Unscheduled and Schedule 2 medicines. It is accepted that these ailments are easily recognised, are unlikely to be confused with more serious conditions and are appropriate for self-selection within pharmacy.
 - Ibuprofen 400 mg with a maximum daily dose of 1200 mg (and limited to 12 tablets) has an excellent safety profile.
 - Ibuprofen has a wide therapeutic index and risk of harm from overdose (intentional or accidental) is minimal. More than 400 mg/kg of ibuprofen needs to be consumed to cause moderate to severe adverse effects. This is significantly more than the 4800 mg contained in a 12 tablet pack of 400 mg double strength tablets.
 - Safety in at risk populations is effectively addressed by product labelling
 - The most commonly used dose of ibuprofen is 400 mg (two tablets of 200 mg XXXXX product), hence availability of the 400 mg dose for self-selection matches consumer use and needs, and is unlikely to alter medication usage.

Australian regulations

- According to the [TGA Ingredient Database](https://www.ebs.tga.gov.au/):⁴⁷
 - Ibuprofen is available for use as an

⁴⁷ TGA Ingredient Database <https://www.ebs.tga.gov.au/>

- § active ingredient in biologicals, export only, over the counter, and prescription medicines;
 - § excipient and equivalent ingredient in biologicals, devices and prescription medicines.
- Ibuprofen lysine is available for use as an
 - § Active ingredient in biologicals, export only, over the counter and prescription medicines
 - § excipient ingredient in biologicals, devices and prescription medicines.
- Ibuprofen sodium dihydrate is available for use as an
 - § active ingredient in biologicals, export only, over the counter and prescription medicines;
 - § excipient ingredient in biologicals and prescription medicines;
 - § equivalent ingredient in biologicals, export only, over the counter and prescription medicines.
- There are 246 medicines currently active on the [Australian Register of Therapeutic Goods \(ARTG\)](#)⁴⁸ that contain ibuprofen as an active ingredient. These include 20 prescription and 221 non-prescription medicines. Ibuprofen is available in the following presentation: tablets (chewable, coated and un-coated), effervescent granules, capsules (chewable and soft), oral liquid and oral suspension (flavoured and un-flavoured) and topical gel.
- Ibuprofen is not permitted to be included in listed medicines as it is not included in the [Therapeutic Goods \(Permissible Ingredients\) Determination](#)⁴⁹ No.1 of 2020.

The [TGA prescribing medicines in pregnancy database](#)⁵⁰ classifies ibuprofen as:

Drug name	Category	Classification Level 1	Classification Level 2	Classification Level 3
Ibuprofen	C	Musculoskeletal System	Non-steriodal anti-inflammatory drugs (NSAIDS)	
<p>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.</p>				

- The [Therapeutic Goods \(Medicines Advisory Statements\) Specification 2019](#)⁵¹ requires the following warning statements pertaining to ibuprofen to be included on the labelling:

⁴⁸ ARTG database <https://www.tga.gov.au/artg>

⁴⁹ Therapeutic Goods (Permissible Ingredients) Determination <https://www.legislation.gov.au/Details/F2020L00150>

⁵⁰ TGA prescribing medicines in pregnancy database <https://www.tga.gov.au/prescribing-medicines-pregnancy-database>

⁵¹ Therapeutic Goods (Medicines Advisory Statements) Specification 2019 <https://www.legislation.gov.au/Details/F2019L00213>

Substance	Conditions	Required Statement(s)
Ibuprofen <i>(Entry 1 of 6)</i>	For the purpose of exclusion from the schedules to the SUSMP, when the preparation is for oral use in adults and children aged 12 years and over.	<ul style="list-style-type: none"> • Do not use if you have a stomach ulcer. • Do not use if you have impaired kidney function. • Do not use if you have heart failure. • Do not use if you are allergic to ibuprofen or other anti-inflammatory medicines. • If you get an allergic reaction, stop taking and see your doctor immediately. • Unless a doctor has told you to, do not use if you have asthma. • Unless advised by your doctor or pharmacist, do not use with products containing ibuprofen, aspirin or other anti-inflammatory medicines or with medicines that you are taking regularly. • Do not use for more than a few days at a time unless a doctor has told you to. Do not exceed the recommended dose. Excessive use can be harmful and increase the risk of heart attack, stroke or liver damage. • Do not use if trying to become pregnant, or during the first 6 months of pregnancy, except on doctor's advice. Do not use at all during the last 3 months of pregnancy. • Unless a doctor has told you to, do not use if you are aged 65 years or over.
Ibuprofen <i>(Entry 2 of 6)</i>	When included in a schedule to the SUSMP for oral use in adults and children aged 12 years and over	<ul style="list-style-type: none"> • Do not use if you have a stomach ulcer. • Do not use if you have impaired kidney function. • Do not use if you have heart failure. • Do not use if you are allergic to ibuprofen or other anti-inflammatory medicines. • If you get an allergic reaction, stop taking and see your doctor immediately. • Unless a doctor has told you to, do not use if you have asthma. • Unless advised by your doctor or pharmacist, do not use with products containing ibuprofen, aspirin or other anti-inflammatory medicines or with medicines that you are taking regularly. • Do not use for more than a few days at a time unless a doctor has told you to. Do not exceed the recommended dose. Excessive use can be

Substance	Conditions	Required Statement(s)
		<p>harmful and increase the risk of heart attack, stroke or liver damage.</p> <ul style="list-style-type: none"> Do not use if trying to become pregnant, or during the first 6 months of pregnancy, except on doctor's advice. Do not use at all during the last 3 months of pregnancy.
<p>Ibuprofen <i>(Entry 3 of 6)</i></p>	<p>For the purpose of exclusion from the schedules to the SUSMP, for oral use in children under 12 years of age</p>	<ul style="list-style-type: none"> Do not use if you have a stomach ulcer. Do not use if you have impaired kidney function. Do not use if you have heart failure. Do not use if you are allergic to ibuprofen or other anti-inflammatory medicines. If you get an allergic reaction, stop taking and see your doctor immediately. Unless a doctor has told you to, do not use if you have asthma. Unless advised by your doctor or pharmacist, do not use with products containing ibuprofen, aspirin or other anti-inflammatory medicines or with medicines that you are taking regularly. Do not use for more than a few days at a time unless a doctor has told you to. Do not exceed the recommended dose. Excessive use can be harmful and increase the risk of heart attack, stroke or liver damage. Do not use if trying to become pregnant, or during the first 6 months of pregnancy, except on doctor's advice. Do not use at all during the last 3 months of pregnancy. Ask your doctor or pharmacist before use of the medicine in children suffering from dehydration through diarrhoea and/or vomiting. Unless a doctor has told you to, do not use if you are aged 65 years or over. Unless a doctor has told you to, do not use in children 6 years of age or less.
<p>Ibuprofen <i>(Entry 4 of 6)</i></p>	<p>When included in a schedule to the SUSMP for oral use in children under 12 years of age</p>	<ul style="list-style-type: none"> Do not use if you have a stomach ulcer. Do not use if you have impaired kidney function. Do not use if you have heart failure. Do not use if you are allergic to ibuprofen or other anti-inflammatory medicines.

Substance	Conditions	Required Statement(s)
		<ul style="list-style-type: none"> • If you get an allergic reaction, stop taking and see your doctor immediately. • Unless a doctor has told you to, do not use if you have asthma. • Unless advised by your doctor or pharmacist, do not use with products containing ibuprofen, aspirin or other anti-inflammatory medicines or with medicines that you are taking regularly. • Do not use for more than a few days at a time unless a doctor has told you to. Do not exceed the recommended dose. Excessive use can be harmful and increase the risk of heart attack, stroke or liver damage. • Do not use if trying to become pregnant, or during the first 6 months of pregnancy, except on doctor's advice. Do not use at all during the last 3 months of pregnancy. • Ask your doctor or pharmacist before use of the medicine in children suffering from dehydration through diarrhoea and/or vomiting.
<p>Ibuprofen (Entry 5 of 6)</p>	<p>In combination with paracetamol, in medicines for oral use</p>	<ul style="list-style-type: none"> • Do not give to children under 12 years of age. • Adults: Keep to the recommended dose. Do not take this medicine for longer than a few days at a time unless advised to by a doctor. • Children and adolescents: Keep to the recommended dose. Do not give this medicine for longer than 48 hours at a time unless advised to by a doctor. • Excessive use can be harmful and increase the risk of heart attack, stroke or liver damage. • Do not use if pregnant or trying to become pregnant. • Do not use if you have a stomach ulcer. • Do not use if you have impaired kidney function. • Do not use if you have heart failure. • Do not use if you are allergic to ibuprofen or other anti-inflammatory medicines. • If you get an allergic reaction, stop taking and see your doctor immediately. • Unless a doctor has told you to, do not use if you have asthma.

Substance	Conditions	Required Statement(s)
		<ul style="list-style-type: none"> Unless a doctor has told you to, do not use if you are aged 65 years or over. Do not take with other products containing paracetamol, ibuprofen, aspirin or other anti-inflammatory medicines or with medicines that you are taking regularly, unless advised to do so by a doctor or pharmacist. If an overdose is taken or suspected, ring the Poisons Information Centre (Australia 13 11 26, New Zealand 0800 764 766) or go to hospital straight away even if you feel well because of the risk of delayed, serious liver damage.
Ibuprofen (Entry 6 of 6)	In preparations for dermal use	<ul style="list-style-type: none"> Do not use [this product/<i>insert name of product</i>] if you are allergic to ibuprofen or other anti-inflammatory medicines. If you get an allergic reaction, stop taking and see your doctor immediately. Unless a doctor or pharmacist has told you to, do not use [this product/<i>insert name of product</i>] with other medicines that you are taking regularly.

- The [Database of Adverse Event Notifications \(DAEN\)](#)⁵² contains 1807 reports of adverse events for products containing ibuprofen as an active ingredient, with 1223 reports where ibuprofen was the single suspected medicine. There were 58 reports of deaths associated with ibuprofen use.
- There are no products containing ibuprofen listed on the [Public Chemical Registration Information System Search \(PubCRIS\)](#).⁵³

International regulations

- According to the [United States Food and Drug Administration Approved Drug Products Database \(Drugs@FDA\)](#)⁵⁴ ibuprofen as single active ingredient is available over-the-counter (OTC) as oral tablet, capsule and suspension preparations. Ibuprofen, in oral tablets and as a solution for intravenous injections, is available as prescription medicines.
- According to the [Canadian \(Health Canada\) Drug Product Database](#)⁵⁵ Ibuprofen, as a single active ingredient, is currently available as a prescription medicine (600 mg table) and over-the-counter-in tablet (50 mg (children's chewable tablet), 200 mg and 400 mg), capsule and/or caplet (200 mg, 400 mg and 600 mg), oral suspension (100 mg/5mL) and paediatric drops (4mg/5mL) presentations.

⁵² Database of Adverse Event Notifications (DAEN) <https://apps.tga.gov.au/Prod/daen/daen-entry.aspx>

⁵³ Public Chemical Registration Information System Search (PubCRIS) <https://portal.apvma.gov.au/pubcris>

⁵⁴ FDA Approved Drug Products Database <https://www.accessdata.fda.gov/scripts/cder/daf/>

⁵⁵ Canadian (Health Canada) Drug Product Database <https://health-products.canada.ca/dpd-bdpp/index-eng.jsp>

- [The European Medicines Agency \(EMA\)](#)⁵⁶ lists ibuprofen and ibuprofen lysine as approved in member states in tablet (200 mg, 400 mg, 600 mg and 800 mg), effervescent granule (400 mg and 600 mg), oral powder (400 mg) and oral suspension (20, 40, 100 and 400 mg/ml, 20 and 100 mg/5 ml) preparations.
- The [World Health Organization's \(WHO\) Model List of Essential Medicines](#)⁵⁷ includes ibuprofen, oral liquid (200 mg/5ml and tablets (200, 400 and 600 mg) for pain and palliative care, ibuprofen tablets (200 and 400 mg) for acute migraine attack (all for use in patients older than 3 months), ibuprofen neonate solution for injection (5 mg/mL).
- According to [New Zealand Medicines and Medical Devices Safety Authority \(MedSafe\)](#)⁵⁸ data base ibuprofen is available as follows:

Ingredient	Conditions	Classification
Ibuprofen	<ul style="list-style-type: none"> • except when specified elsewhere in this schedule 	Prescription
Ibuprofen	<ul style="list-style-type: none"> • for oral use in tablets or capsules containing up to 400 milligrams per dose form and in packs containing not more than 50 dose units and that have received the consent of the Minister or the Director-General to their distribution as restricted medicines and that are sold in the manufacturer's original pack labelled for use by adults and children over 12 years of age 	Restricted
Ibuprofen	<ul style="list-style-type: none"> • for oral use in liquid form with a recommended daily dose of not more than 1.2 grams for the relief of pain and reduction of fever or inflammation when sold in the manufacturer's original pack containing not more than 8 grams; • for oral use in solid dose form containing not more than 200 milligrams per dose form and with a recommended daily dose of not more than 1.2 grams when sold in the manufacturer's original pack containing not more than 100 dose units; • except in divided solid dosage forms for oral use containing 200 milligrams or less per dose form with a recommended daily dose of not more than 1.2 grams and when sold in the manufacturer's original pack containing not more than 25 dose units 	Pharmacy Only
Ibuprofen	<ul style="list-style-type: none"> • for external use; • in divided solid dosage forms for oral use containing 200 milligrams or less per dose form with a recommended daily dose of not more than 1.2 grams and when sold in the manufacturer's original pack containing not more than 25 dose units per pack 	General Sale

⁵⁶ European Medicines Agency <https://www.ema.europa.eu/en>

⁵⁷ The WHO Model List of Essential Medicines <https://www.who.int/medicines/publications/essentialmedicines/en/>

⁵⁸ New Zealand Medicines and Medical Devices Safety Authority (MedSafe) <https://www.medsafe.govt.nz/profs/class/classintro.asp>

1.6 Cumyl-pegacalone

CAS Number

2160555-55-3

Alternative names

2,5-Dihydro-2-(1-methyl-1-phenylethyl)-5-pentyl-1H-pyrido[4,3-b]indol-1-one; SGT-151

Applicant

N/A - Initiated by the Delegate of the Secretary of the Commonwealth Department of Health

Current scheduling

Cumyl pegaclone is not specifically scheduled in the current Poisons Standard. However, it is captured by the following group entry in the Poisons Standard:

Schedule 9

SYNTHETIC CANNABINOMIMETICS **except** when separately specified in these Schedules.

Index

SYNTHETIC CANNABINOMIMETICS

Schedule 9

Proposed scheduling

Schedule 9 – New Entry

2,5-DIHYDRO-2-(1-METHYL-1-PHENYLETHYL)-5-PENTYL-1H-PYRIDO[4,3-B]INDOL-1-ONE (CUMYL-PEGACLONE)

Index – New Entry

2,5-DIHYDRO-2-(1-METHYL-1-PHENYLETHYL)-5-PENTYL-1H-PYRIDO[4,3-B]INDOL-1-ONE (CUMYL-PEGACLONE)

Schedule 9

Key uses/expected use

New Psychoactive Substance

Reasons for the proposal

- Cumyl pegaclone is considered a synthetic cannabinoid and New Psychoactive Substance (NPS). There is evidence that its consumption has resulted in adverse health outcomes, with multiple presentations to emergency departments in metropolitan and regional hospitals.
- Following consumption patients are typically agitated, exhibit bizarre behaviours and experience delusions and hallucinations.
- There have been reports that certain businesses are covertly selling this substance to vulnerable populations, such as those experiencing homelessness and young people, including children.

- Cumyl pegaclone is currently captured under the Schedule 9 entry for synthetic cannabinomimetics. To remove any potential ambiguity about the scheduling status of cumyl pegaclone, it is proposed that a new Schedule 9 entry be created.
- Cumyl pegaclone has no legitimate medical, industrial, agricultural or cosmetic uses. Inclusion in Schedule 9 would still allow *bona fide* researchers to be authorised to use this chemical.

Australian regulations

- Cumyl pegaclone is not listed as an ingredient on the [TGA Ingredient Database](#)⁵⁹
- There are no medicines currently active on the [Australian Register of Therapeutic Goods \(ARTG\)](#)⁶⁰ that contain cumyl pegaclone as an active ingredient.
- Cumyl pegaclone is not permitted to be included in listed medicines as it is not included in the [Therapeutic Goods \(Permissible Ingredients\) Determination](#)⁶¹ No.1 of 2020.
- There are no warning statements pertaining to cumyl pegaclone in the [Therapeutic Goods \(Medicines Advisory Statements\) Specification 2019](#)⁶²
- The [Database of Adverse Event Notifications \(DAEN\)](#)⁶³ contains no reports of adverse events for products containing cumyl pegaclone as an active ingredient.
- There are no products containing cumyl pegaclone listed on the [Public Chemical Registration Information System Search \(PubCRIS\)](#).⁶⁴

International regulations

- In Canada, cumyl pegaclone is included in Schedule II of the Controlled Drugs and Substances Act.
- Cumyl pegaclone is listed in the annex of the German Narcotics Law (Betäubungsmittelgesetz, BtMG).
- The Public Health Agency of Sweden classified cumyl pegaclone as a narcotic on 18 January 2019.
- Cumyl pegaclone is captured under the United Kingdom Psychoactive Substances Act 2016 and the New Zealand *Psychoactive Substances Act 2013*.

⁵⁹ TGA Ingredient Database <https://www.ebs.tga.gov.au/>

⁶⁰ ARTG database <https://www.tga.gov.au/artg>

⁶¹ Therapeutic Goods (Permissible Ingredients) Determination [https://www.legislation.gov.au/Search/Therapeutic%20Goods%20LB\\$Permissible%20Ingredients\\$RB%20Determination](https://www.legislation.gov.au/Search/Therapeutic%20Goods%20LB$Permissible%20Ingredients$RB%20Determination)

⁶² Therapeutic Goods (Medicines Advisory Statements) Specification 2019 <https://www.legislation.gov.au/Details/F2019L00213>

⁶³ Database of Adverse Event Notifications (DAEN) <https://apps.tga.gov.au/Prod/daen/daen-entry.aspx>

⁶⁴ Public Chemical Registration Information System Search (PubCRIS) <https://portal.apvma.gov.au/pubcris>

2. Proposed amendments referred for scheduling advice to the Joint ACMS-ACCS #25

2.1 Nicotine

CAS Number

54-11-5

Alternative names

3-[[2S]-1-methylpyrrolidin-2-yl]pyridine [IUPAC]

Applicant

N/A – Initiated by the Delegate of the Secretary of the Commonwealth Department of Health

Current scheduling

Schedule 7

NICOTINE **except**:

- a) when included in Schedule 6;
- b) in preparations for human therapeutic use; or
- c) in tobacco prepared and packed for smoking.

Schedule 6

NICOTINE in preparations containing 3 per cent or less of nicotine when labelled and packed for the treatment of animals.

Schedule 4

NICOTINE in preparations for human therapeutic use **except** for use as an aid in withdrawal from tobacco smoking in preparations for oromucosal or transdermal use.

Appendix F, Part 3

Poison	Safety Direction
NICOTINE except when in tobacco.	1 (Avoid contact with eyes); 4 (Avoid contact with skin)

Appendix J, Part 2

NICOTINE

INDEX

NICTOINE

Schedule 7

Schedule 6

Schedule 4

Appendix F, Part 3

Appendix J, Part 2

Proposed scheduling

Schedule 7 – Amend Entry

NICOTINE **except:**

- ~~a) when included in Schedule 6;~~
- a) when included in Schedule 4 in preparations for human therapeutic use; or
- b) in tobacco prepared and packed for smoking; or
- c) for human therapeutic use as an aid in withdrawal from tobacco smoking in preparations for oromucosal or transdermal use.

Schedule 6 – Delete Entry

~~NICOTINE in preparations containing 3 per cent or less of nicotine when labelled and packed for the treatment of animals.~~

Schedule 4 – Amend Entry

NICOTINE in preparations for human therapeutic use **except:**

- a) when for human therapeutic use as an aid in withdrawal from tobacco smoking in preparations for oromucosal or transdermal use; or
- b) in tobacco prepared and packed for smoking.

Appendix D, Item 5 – New Entry

Nicotine when included in Schedule 4.

Key uses/expected use

N/A

Reasons for the proposal

- To clarify the access controls for nicotine in Australia.
- It is proposed to delete the Schedule 6 nicotine entry. The Schedule 6 entry is not required as there are no longer products containing nicotine for the treatment of animals.
- The proposed amendment clarifies that nicotine for human use, other than tobacco for smoking, is only exempt from Schedule 4 when it is included in oromucosal and transdermal preparations for smoking cessation.
- The proposed amendment does not change the current exemption from scheduling for tobacco prepared and packed for smoking.
- The proposed amendment to include a new entry for nicotine in Appendix D, Item 5 will ensure that possession of Schedule 4 products containing nicotine must be in accordance with a legal prescription.
- The proposed amendment does not impact the current regulatory pathways for approval of nicotine containing therapeutic products.

- The proposed amendment is separate to, and does not pre-empt, the consideration of a prior application to reschedule nicotine, published on [20 December 2019](#),⁶⁵.

Australian regulations

- According to the [TGA Ingredient Database](#),⁶⁶ nicotine is:
 - available for use as an active ingredient in: biologicals, export only, over the counter, prescription medicines;
 - available for use as an excipient ingredient in: biologicals, devices, prescription medicines; and
 - not available as an equivalent ingredient in any application.
- According to the [TGA Ingredient Database](#), nicotine betadex complex is:
 - available for use as an active ingredient in: biologicals, export only, over the counter, prescription medicines;
 - available for use as an excipient ingredient in: biologicals, devices, prescription medicines; and
 - not available as an equivalent ingredient in any application.
- According to the [TGA Ingredient Database](#), nicotine bitartrate dehydrate is:
 - available for use as an active ingredient in: biologicals, export only, over the counter, prescription medicines;
 - available for use as an excipient ingredient in: biologicals, prescription medicines; and
 - not available as an equivalent ingredient in any application.
- According to the [TGA Ingredient Database](#), nicotine polacrilex is:
 - available for use as an active ingredient in: biologicals, export only, over the counter, prescription medicines;
 - available for use as an excipient ingredient in: biologicals, devices, prescription medicines; and
 - not available as an equivalent ingredient in any application.
- There are 122 medicines currently active on the [Australian Register of Therapeutic Goods \(ARTG\)](#)⁶⁷ that contain nicotine, nicotine betadex complex, nicotine bitartrate dehydrate and nicotine polacrilex as an active ingredient. These include 2 export-only medicines and 120 non-prescription medicines. Nicotine is available in the following formulations: sublingual tablets, transdermal patches, chewing gum, lozenge, buccal inhalation and aerosol spray (Attachment A).

⁶⁵ Pre-meeting public notice - December 2019: <https://www.tga.gov.au/consultation-invitation/consultation-proposed-amendments-poisons-standard-accs-acms-and-joint-acmsaccs-meetings-march-2020>

⁶⁶ TGA Ingredient Database <https://www.ebs.tga.gov.au/>

⁶⁷ ARTG database <https://www.tga.gov.au/artg>

- In Pharmacy Only preparations for inhalation except when sold from a smoking cessation clinic run under the auspices of a registered medical practitioner, nurse, pharmacist or psychologist
- Prescription formulations for nasal use

United Kingdom (U.K)

Nicotine is available as a replacement therapy in general sale, pharmacy and prescription medicine preparations. Nicotine is available in the following formulations: skin patches, chewing gum, inhalators, tablets, oral strips, lozenges, nasal and mouth sprays.

2.2 Cannabidiol

CAS Number

13956-29-1

Alternative names

CBD; 2-(6-Isopropenyl-3-methyl-2-cyclohexen-1-yl)-5-pentyl-1,3-benzenediol

Applicant

Private applicant

Current scheduling

Cannabis

Schedule 9

CANNABIS (including seeds, extracts, resins, and the plant and any part of the plant when packed or prepared), **except:**

- a) when separately specified in these Schedules; or
- b) processed hemp fibre containing 0.1 per cent or less of tetrahydrocannabinols and hemp fibre products manufactured from such fibre; or
- c) when in hemp seed oil for purposes other than internal human use containing 50 mg/kg or less of cannabinoids, including 20 mg/kg or less of tetrahydrocannabinols, when labelled with either of the following warning statements:
 - ii) Not for internal use; or
 - iii) Not to be taken.

Schedule 8

CANNABIS (including seeds, extracts, resins and the plant, and any part of the plant) when prepared or packed for human therapeutic use, when:

- a) cultivated or produced, or in products manufactured⁷³, in accordance with the *Narcotic Drugs Act 1967*; and/or

⁷³ "Cultivation", "production" and "manufacture" have the same meaning as in the *Narcotic Drugs Act 1967*

- b) for use in products manufactured in accordance with the *Narcotic Drugs Act 1967*; and/or
- c) imported as therapeutic goods, or for use in therapeutic goods, for supply, in accordance with the *Therapeutic Goods Act 1989*; and/or
- d) in therapeutic goods supplied in accordance with the *Therapeutic Goods Act 1989*,
except when:
 - i) it is in a product to which item 4, 8, 10, 11 or 12 of Schedule 5A to the *Therapeutic Goods Regulations 1990* applies; or
 - ii) separately specified in the NABIXIMOLS entry in this Schedule; or
 - iii) captured by the CANNABIDIOL entry in Schedule 4.

Appendix D, Item 1 (Poisons available only from or on the prescription or order of an authorised medical practitioner)

CANNABIS for human use.

Appendix K

CANNABIS **except** cannabidiol when included in Schedule 4

Index

CANNABIS

cross reference: CANNABIS SATIVA, HEMP, HEMP SEED OIL, TETRAHYDROCANNABINOLS

Schedule 9

Schedule 8

Appendix D, Item 1

Appendix K

Cannabidiol

Schedule 4

CANNABIDIOL in preparations for therapeutic use where:

- a) cannabidiol comprises 98 per cent or more of the total cannabinoid content of the preparation; and
- b) any cannabinoids, other than cannabidiol, must be only those naturally found in cannabis and comprise 2 per cent or less of the total cannabinoid content of the preparation.

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CANNABIDIOL

cross reference: NABIXIMOLS, CANNABIS, TETRAHYDROCANNABINOLS

Schedule 4

Proposed scheduling

Schedule 8 – Amend Entry

CANNABIS (including seeds, extracts, resins and the plant, and any part of the plant) when prepared or packed for human therapeutic use, when:

- a) cultivated or produced, or in products manufactured⁷⁴, in accordance with the *Narcotic Drugs Act 1967*; and/or
- b) for use in products manufactured in accordance with the *Narcotic Drugs Act 1967*; and/or
- c) imported as therapeutic goods, or for use in therapeutic goods, for supply, in accordance with the *Therapeutic Goods Act 1989*; and/or
- d) in therapeutic goods supplied in accordance with the *Therapeutic Goods Act 1989*,

except when:

- i) it is in a product to which item 4, 8, 10, 11 or 12 of Schedule 5A to the *Therapeutic Goods Regulations 1990* applies; or
- ii) separately specified in the NABIXIMOLS entry in this Schedule; or
- iii) captured by the CANNABIDIOL entry in Schedule 4; **or**
- iv) **it is a whole plant cannabis product or distillate or isolate which contains at least 98 per cent cannabidiol and less than or equal to 0.2 per cent tetrahydrocannabinol (THC).**

Schedule 4 – Amend Entry

CANNABIDIOL in preparations for therapeutic use where:

- a) cannabidiol comprises 98 per cent or more of the total cannabinoid content of the preparation **and any cannabinoids, other than cannabidiol, must be only those naturally found in cannabis and comprise 2 per cent or less of the total cannabinoid content of the preparation; or**
- b) ~~any cannabinoids, other than cannabidiol, must be only those naturally found in cannabis and comprise 2 per cent or less of the total cannabinoid content of the preparation.~~ **cannabidiol is a synthetic or semi-synthetic copy of the molecule and comprises 98 per cent or more of the total cannabinoid content of the preparation and any other synthetic or semi-synthetic cannabinoids, other than cannabidiol, must comprise 2 per cent or less of the total cannabinoid content of the preparation.**

except when cannabidiol comprises 98 per cent or more of the total cannabinoid content and the tetrahydrocannabinol (THC) content is less than or equal to 0.2 per cent of the total cannabinoid content of the preparation.

Key uses/expected use

Medicines

Reasons for the proposal put forward by the Applicant

- The benefit/risk ratio is such that cannabidiol (CBD) formulations in which 98% or greater of the cannabinoid content is CBD and where the upper limit to THC content is 0.2% (by dry weight), should not be regulated as an unapproved medicine through its inclusion on Schedule 4 of the SUSMP, but instead, regulated as listed, assessed-listed or registered

⁷⁴ "Cultivation", "production" and "manufacture" have the same meaning as in the *Narcotic Drugs Act 1967*

medicines (depending on the level of therapeutic claim) under the Australian Register of Therapeutic Goods (ARTG).

- Given its clear evidence of benefits, good safety profile and low risk, it should be regulated as a complementary medicine in the same way that other plant medicines (herbal medicines) are regulated in Australia.
- The potential benefits of removing plant-derived CBD from the Poisons Standard and instead regulating it as other herbal medicines and complementary medicines are regulated (listed, assess-listed or registered on the ARTG) is that this will substantially increase its access and reduce costs to the consumer.
- Regulation of CBD as a complementary medicine will allow its prescription by other qualified healthcare practitioners such as western herbal medicine practitioners and registered Chinese herbal medicine practitioners, consistent with their scope of practice, and further increase access to patients.
- This amendment would allow the same level of access to CBD products as is enjoyed in many western countries including the US and countries within Europe where hemp-derived CBD products may be purchased over the counter or online.
- Concerns about potential drug-CBD interactions can be handled effectively through limiting the amount of CBD able to be sold in a month's supply and the inclusion of appropriate warning labels.
- It is suggested that the Schedule 4 entry for CBD be reworded to explicitly include (future) synthetic or semi-synthetic formulations.
- The entry in relation to cannabis in Schedule 8 of the SUSMP may also require rewording to explicitly exempt whole plant cannabis products or distillates or isolates which contain at least 98% CBD and less than or equal to 0.2% THC.

Australian regulations

- According to the [TGA Ingredient Database](#),⁷⁵ cannabidiol is:
 - Available for use as an active ingredient in export only and prescription medicines
 - Not available as an excipient ingredient in any application
 - Not available as an equivalent ingredient in any application
- As of 1 April 2020, there are 6 medicines currently active on the [Australian Register of Therapeutic Goods \(ARTG\)](#)⁷⁶ that contain cannabidiol as an active ingredient. These are all export only medicines.
- Cannabidiol is not permitted to be included in listed medicines as it is not included in the [Therapeutic Goods \(Permissible Ingredients\) Determination](#)⁷⁷ No.1 of 2020.
- Cannabidiol is not included on the [TGA prescribing medicines in pregnancy database](#).⁷⁸

⁷⁵ TGA Ingredient Database <https://www.ebs.tga.gov.au/>

⁷⁶ ARTG database <https://www.tga.gov.au/artg>

⁷⁷ Therapeutic Goods (Permissible Ingredients) Determination

[https://www.legislation.gov.au/Search/Therapeutic%20Goods%20LB\\$Permissible%20Ingredients\\$RB\\$%20Determination](https://www.legislation.gov.au/Search/Therapeutic%20Goods%20LB$Permissible%20IngredientsRB%20Determination)

⁷⁸ TGA prescribing medicines in pregnancy database <https://www.tga.gov.au/prescribing-medicines-pregnancy-database>

- There are no warning statements pertaining to cannabidiol in the [Therapeutic Goods \(Medicines Advisory Statements\) Specification 2019](#).⁷⁹
- As of 1 April 2020, there were no reports of adverse events for products containing cannabidiol as an active ingredient on the [Database of Adverse Event Notifications \(DAEN\)](#).⁸⁰
- As of 1 April 2020, there were no products containing cannabidiol listed on the [Public Chemical Registration Information System Search \(PubCRIS\)](#).⁸¹

International regulations

- In a letter dated 24 Jan 2019 from the Director General of the WHO to the Secretary General of the United Nations, on the basis of the 12 to 16 November 2018 reviews conducted by the WHO's Expert Committee on Drug Dependence (ECDD) on cannabis and cannabis related substances (including CBD), the WHO recommended that preparations containing predominantly CBD with not more than 0.2% THC should not be placed under international drug control (WHO 2019)⁸²:

“To give effect to the recommendation of the fortieth meeting of the ECDD that preparations considered to be pure cannabidiol (CBD) should not be scheduled within the International Drug Control Conventions by adding a footnote to the entry for cannabis and cannabis resin in Schedule I of the Single Convention on Narcotic Drugs (1961) to read “Preparations containing predominantly cannabidiol and not more than 0.2 percent of delta-9-tetrahydrocannabinol are not under international control””

- In New Zealand cannabidiol is classified as a prescription only medicine, where the tetrahydrocannabinols (THCs) and specified substances within the product must not exceed 2 percent of the total CBD, tetrahydrocannabinol (THC) and other specified substances. If a product contains CBD but does not meet the definition of a CBD product, it is a ‘controlled drug’ and is subject to the regulatory requirements of the Misuse of Drugs Act.
- In the United States (U.S) the FDA has approved only one CBD product, a prescription drug product to treat two rare, severe forms of epilepsy. It is currently illegal to market CBD by adding it to a food or labelling it as a dietary supplement. Some CBD products are being marketed with unproven medical claims and are of unknown quality. In 2018, the *Farm Bill* legalized the production and sale of hemp and its extracts. Hemp derived CBD containing less than 0.3 percent THC, is exempted under federal law, however some states still have legal restrictions on the possession of CBD.
- In Canada, there is one approved product containing a CBD/THC combination, available as a prescription medicine. Phytocannabinoids are regulated under the Cannabis Act. Under the Cannabis Act, CBD products remain strictly regulated and are only legal when sold in compliance with the Act and its regulations. The provinces and territories are responsible for determining how cannabis is distributed and sold within their jurisdictions. CBD and products containing CBD, such as cannabis oil, may only be sold by a provincially or territorially-authorized cannabis retailer or a federally-licensed seller of cannabis for medical purposes.
- The European Union guides all member states that hemp should not exceed a THC limit of 0.2%. In January 2019, European Union’s Novel Food regime, led to the classification of all extracted cannabinoids as “novel”. Novel Food is defined as food that had not been used for

⁷⁹ Therapeutic Goods (Medicines Advisory Statements) Specification 2019 <https://www.legislation.gov.au/Details/F2019L00213>

⁸⁰ Database of Adverse Event Notifications (DAEN) <https://apps.tga.gov.au/Prod/daen/daen-entry.aspx>

⁸¹ Public Chemical Registration Information System Search (PubCRIS) <https://portal.apvma.gov.au/pubcris>

⁸² https://www.who.int/medicines/access/controlled-substances/UNSG_letter_ECDD41_recommendations_cannabis_24Jan19.pdf?ua=1

human consumption to a significant degree in the European Union before 15th May 1997. According to this new classification, CBD products require pre-market authorisation

- In the United Kingdom (U.K), CBD in its pure form is not classed as a controlled drug. The limit on THC content is set at 1mg of THC per container limit. The UK Food Standards Agency has set a deadline on 21 March 2021 for companies marketing CBD extracts as foods or foods supplements, to submit Novel Food approval applications.

2.3 Methylisothiazolinone and methylchloroisothiazolinone

CAS Number

Methylisothiazolinone: 2682-20-4

Methylchloroisothiazolinone: 26172-55-4

Alternative names

Methylisothiazolinone: 3-Isothiazolone, 2-methyl-; 2-methyl-3-isothiazolone; MI

Methylchloroisothiazolinone: 3(2H)-Isothiazolone, 5-chloro-2-methyl-; 5-chloro-2-methyl-3-isothiazolone; MCI

Applicant

N/A - Initiated by the Delegate of the Secretary of the Commonwealth Department of Health with advice from the National Industrial Chemicals Notification and Assessment Scheme (NICNAS).

Current scheduling

Schedule 6

METHYLISOTHIAZOLINONE except:

- a) in rinse-off cosmetic preparations or therapeutic goods intended for topical rinse-off application containing 0.0015 per cent or less of methylisothiazolinone; or
- b) in other preparations that are not intended for direct application to the skin containing 0.1 per cent or less of methylisothiazolinone.

Schedule 6

METHYLCHLOROISOTHIAZOLINONE except:

- a) in rinse-off cosmetic preparations or therapeutic goods intended for topical rinse-off application containing 0.0015 per cent or less of methylchloroisothiazolinone and methylisothiazolinone in total; or
- b) in other preparations that are not intended for direct application to the skin containing 0.1 per cent or less of methylchloroisothiazolinone and methylisothiazolinone in total.

Appendix F, Part 3

Poison	Warning statements	Safety direction
METHYLISOTHIAZOLINONE.	28	

Poison	Warning statements	Safety direction
28: (Over) (Repeated) exposure may cause sensitisation.		

Index

METHYLCHLOROISOTHIAZOLINONE

cross reference: METHYLISOTHIAZOLINONE

Schedule 6

Appendix F, Part 3

METHYLISOTHIAZOLINONE

cross reference: METHYLCHLOROISOTHIAZOLINONE

Schedule 6

Appendix F, Part 3

Proposed scheduling

Schedule 6 – Amend Entry

METHYLISOTHIAZOLINONE **except:**

- in rinse-off cosmetic preparations or therapeutic goods intended for topical rinse-off application containing 0.0015 per cent or less of methylisothiazolinone; or
- in other preparations that are not intended for direct application to the skin containing ~~0.1~~ **0.05** per cent or less of methylisothiazolinone **isothiazolinones in total when labelled with the statements:**

CONTAINS ISOTHIAZOLINONES

REPEATED EXPOSURE MAY CAUSE SENSITISATION

(written in letters not less than 1.5 mm in height)

Appendix F, Part 3 – Amend Entry

Poison	Warning statements	Safety direction
METHYLISOTHIAZOLINONE.	28 X	
28: (Over) (Repeated) exposure may cause sensitisation. X: CONTAINS ISOTHIAZOLINONES REPEATED EXPOSURE MAY CAUSE SENSITISATION (written in letters not less than 1.5 mm in height)		

Schedule 6 – Amend Entry

METHYLCHLOROISOTHIAZOLINONE **except:**

- a) in rinse-off cosmetic preparations or therapeutic goods intended for topical rinse-off application containing 0.0015 per cent or less of methylchlorisothiazolinone and methylisothiazolinone in total; or
- b) in other preparations that are not intended for direct application to the skin containing ~~0.1~~ **0.05** per cent or less of ~~methylchlorisothiazolinone and methylisothiazolinone in total.~~ **isothiazolinones in total when labelled with the statements:**

CONTAINS ISOTHIAZOLINONES

REPEATED EXPOSURE MAY CAUSE SENSITISATION

(written in letters not less than 1.5 mm in height)

Appendix F, Part 3 – Amend Entry

Poison	Warning statements	Safety direction
METHYLISOTHIAZOLINONE.	28 X	
<p>28: (Over) (Repeated) exposure may cause sensitisation.</p> <p>X: CONTAINS ISOTHIAZOLINONES</p> <p>REPEATED EXPOSURE MAY CAUSE SENSITISATION</p> <p>(written in letters not less than 1.5 mm in height)</p>		

Key uses/expected use

Cosmetic, domestic and industrial

Reasons for the proposal

- Isothiazolinones are known skin sensitisers and there is a high skin sensitisation incidence (newly diagnosed cases) and prevalence (already sensitised) around the world.
- The cut-off value of 0.05 per cent for preparations not intended for direct application to the skin, takes into account the minimum patch test concentrations used to elicit sensitisation reactions in patients with allergies to isothiazolinones.
- The proposed warning statement is intended to allow persons who know they have previously been sensitised to isothiazolinones to avoid elicitation by taking additional care or by choosing a different product.

Australian regulations

- According to the [TGA Ingredient Database](https://www.ebs.tga.gov.au/),⁸³ methylisothiazolinone and methylchlorisothiazolinone are:
 - Available for use as an active ingredient in biologicals and prescription medicines
 - Available for use as an excipient ingredient in: biologicals, devices, export only, listed medicines, over the counter and prescription medicines

⁸³ TGA Ingredient Database <https://www.ebs.tga.gov.au/>

- Not available as an equivalent ingredient in any application
- As of March 2020, there are 40 medicines currently active on the [Australian Register of Therapeutic Goods \(ARTG\)](#)⁸⁴ that contain methylisothiazolinone as an active ingredient. These include 20 export only medicines, 11 listed medicines, seven (7) medical devices, one (1) non-prescription medicine and one (1) other therapeutic good (OTG) device.
- As of March 2020, there were 19 medicines currently active on the [Australian Register of Therapeutic Goods \(ARTG\)](#)⁸⁵ that contain methylchloroisothiazolinone as an active ingredient. These include two (2) export only medicines, ten (10) listed medicines, six (6) medical devices and one (1) other therapeutic good (OTG) device.
- According to the [Therapeutic Goods \(Permissible Ingredients\) Determination](#)⁸⁶ No.1 of 2020, methylisothiazolinone and methylchloroisothiazolinone are permitted to be included in listed medicines as follows:

Item	Ingredient name	Purpose	Specific requirements
3340	METHYLISOTHIAZOLINONE	E	Only for use in topical medicines for dermal application that are rinsed off the skin. The total concentration of methylchloroisothiazolinone and methylisothiazolinone in the medicine must be no more than 0.0015%.
3336	METHYLCHLOROISOTHIAZOLINONE	E	Only for use in topical medicines for dermal application that are rinsed off the skin. The total concentration of methylchloroisothiazolinone and methylisothiazolinone in the medicine must be no more than 0.0015%
E = excipient for a medicine meaning an ingredient that is not an active ingredient or a homoeopathic preparation ingredient			

- There are no warning statements pertaining to methylisothiazolinone and methylchloroisothiazolinone in the [Therapeutic Goods \(Medicines Advisory Statements\) Specification 2019](#)⁸⁷
- As of March 2020, there were no reports of adverse events for products containing methylisothiazolinone and methylchloroisothiazolinone as an active ingredient on the [Database of Adverse Event Notifications \(DAEN\)](#)⁸⁸

⁸⁴ ARTG database <https://www.tga.gov.au/artg>

⁸⁵ ARTG database <https://www.tga.gov.au/artg>

⁸⁶ Therapeutic Goods (Permissible Ingredients) Determination

[https://www.legislation.gov.au/Search/Therapeutic%20Goods%20LB\\$Permissible%20Ingredients\\$RB\\$%20Determination](https://www.legislation.gov.au/Search/Therapeutic%20Goods%20LB$Permissible%20IngredientsRB%20Determination)

⁸⁷ Therapeutic Goods (Medicines Advisory Statements) Specification 2019 <https://www.legislation.gov.au/Details/F2019L00213>

⁸⁸ Database of Adverse Event Notifications (DAEN) <https://apps.tga.gov.au/Prod/daen/daen-entry.aspx>

- As of March 2020, there were no products containing methylisothiazolinone and methylchloroisothiazolinone listed on the [Public Chemical Registration Information System Search \(PubCRIS\)](#).⁸⁹

International regulations

Europe

- In the European Union (EU), MI, as well as the mixture of MCI and MI (in the ratio of 3:1) (mixture defined by CAS No. 55965-84-9) are listed on Annex V (List of preservatives allowed in cosmetic products) to Regulation No. 1223/2009 on cosmetic products, with a maximum concentration permitted in rinse-off products of 0.0015 %.
- The Scientific Committee on Consumer Safety (SCCS) concluded in 2015 that it does not support the safe use of MI as a preservative in rinse-off cosmetic products up to a concentration limit of 100 ppm from the view of induction of contact allergy. For rinse-off cosmetic products, a concentration of 15 ppm (0.0015%) MI is considered safe for the consumer from the point of view of induction of contact allergy. It was not safe to use MI as a preservative in leave-on hair cosmetic products up to a concentration limit of 100 ppm (0.01%) from the point of view of induction of contact allergy.
- An application for approval of use of MI as a preservative for products during storage is in progress; this may include paint products. MI is approved for use as a biocide in the European Economic Area and/or Switzerland, for: preservation for liquid systems, controlling slimes, preservation for working / cutting fluids.
- According to the European Chemicals Agency (ECHA, 2019) Biocidal Active Substances database, the mixture of MCI/MI (ratio of 3:1) is approved for use as a preservative for products during storage; this approval includes use in paints and coatings. Additionally, as a condition of approval for non-professional users, the end-use concentration of MCI/MI in the preserved product (paints and coatings, liquid detergents, adhesives and sealants and household products) must be reduced below the concentration limit of 0.0015% (15 ppm), in order to take into account the sensitising properties of MCI/MI.
- The Committee for Risk Assessment (RAC) and the Committee for Socio-economic Analysis (SEAC) have proposed to prohibit substances classified as skin sensitisers for use in tattoo and PMU inks (RAC and SEAC, 2019).

Canada

- MI, as well as the combination of MCI and MI (MCI/MI), are listed on Health Canada's List of Ingredients that are Restricted for Use in Cosmetic Products (Cosmetic Ingredient Hotlist), with a maximum concentration of 0.0015 % in rinse-off products; neither MI or MCI/MI are permitted in leave-on products. Additionally, if MI is present in formulation with MI/MCI in combination, the cumulative total concentration of MI and MI/MCI may not exceed 0.0015 %. MCI is only permitted when present in combination with MI (Health Canada, 2019).

United States (US)

- A 2019 Cosmetic Ingredient Review (CIR) report concluded that MI is safe for use in rinse-off cosmetic products at concentrations up to 100 ppm. The report also recommended a concentration of 15 ppm MCI/MI (76.7 % MCI and 23.3 % MI) for cosmetic rinse-off products and ≤7.5 ppm in cosmetic leave-on products.

⁸⁹ Public Chemical Registration Information System Search (PubCRIS) <https://portal.apvma.gov.au/pubcris>

- The US Environmental Protection Agency (EPA) lists MI and MCI as approved antimicrobial agents.

2.4 Isothiazolinones

Applicant

N/A - Initiated by the Delegate of the Secretary of the Commonwealth Department of Health with advice from the National Industrial Chemicals Notification and Assessment Scheme (NICNAS)

Current scheduling

An isothiazolinones group entry does not exist in the current Poisons Standard.

Five isothiazolinones are separately scheduled in the current Poison Standard. These are:

- Methylisothiazolinone, which is currently listed in:
 - Schedule 6
 - Appendix F, Part 3
- Methylchloroisothiazolinone, which is currently listed in:
 - Schedule 6
 - Appendix F, Part 3
- 4,5-dichloro-2-n-octyl-3(2H)-isothiazolone, which is currently listed in:
 - Schedule 6
- Octhilinone
 - Schedule 6
- Benzisothiazolinone and 2-methyl-1,2-benzisothiazol-3-one are not specifically scheduled in the current Poisons Standard.

Proposed scheduling

Schedule 6 – New Entry

ISOTHIAZOLINONES not elsewhere specified in these Schedules, **except** in preparations that are not intended for direct application to the skin containing 0.05 per cent or less of isothiazolinones in total and labelled with the statements:

CONTAINS ISOTHIAZOLINONES

REPEATED EXPOSURE MAY CAUSE SENSITISATION

(written in letters not less than 1.5 mm in height)

Index – New Entry

ISOTHIAZOLINONES

Cross-reference: METHYLISOTHIAZOLINONE, METHYLCHLOROISOTHIAZOLINONE, BENZISOTHIAZOLINONE, 2-METHYL-1,2-BENZISOTHIAZOL-3-ONE, 4,5-DICHLORO-2-N-OCTYL-3(2H)-ISOTHIAZOLONE, OCTHILINONE

Schedule 6

Appendix F, Part 3 – New Entry

Poison	Warning statements	Safety direction
ISOTHIAZOLINONES	X	
X: CONTAINS ISOTHIAZOLINONES REPEATED EXPOSURE MAY CAUSE SENSITISATION (written in letters not less than 1.5 mm in height)		

Schedule 6 – Delete Entry

~~OCTHILINONE except in paints, jointing compounds and sealants containing 1 per cent or less of octhiline calculated on the non-volatile content.~~

Schedule 6 – Delete Entry

~~4,5-DICHLORO-2-N-OCTYL-3(2H)-ISOTHIAZOLONE.~~

Key uses/expected use

Cosmetic, domestic and industrial

Reasons for the proposal

- Isothiazolinones are known skin sensitisers and there is a high skin sensitisation incidence (newly diagnosed cases) and prevalence (already sensitised) around the world.
- There is a potential for cross-sensitisation between isothiazolinones in individuals. Due to the potential for cross-sensitisation between the isothiazolinones, they should be considered together as a group (including all isothiazolinone preservatives on the Australian Inventory of Chemical Substances (AICS)) for the purpose of amending the current schedule entries and adding a new entry for isothiazolinones in Schedule 6.
- Cosmetic and domestic products including paints contain combinations of isothiazolinones.
- There is a risk of sensitisation in consumers, particularly for those using paint products containing a combination of isothiazolinones.
- Certain isothiazolinones are unscheduled and should be included in Schedule 6 to restrict their use.
- Similar scheduling restrictions for all isothiazolinones in preparations not intended for direct skin application are recommended.

Australian regulations

As of March 2020:

([Drugs@FDA](#))⁹⁸ do not specifically identify isothiazolinones, benzisothiazolinone or 2-methyl-1,2-benzisothiazol-3-one.

Europe

In Europe, benzisothiazolinone is available for use as an antimicrobial agent in cosmetics according to the [European Commission database for information on cosmetic substances and ingredients database](#).⁹⁹ The European Scientific Committee on Consumer Safety (SCCS), in its evaluation of benzisothiazolinone conducted in June 2012, considered that benzisothiazolinone was safe for use as a preservative in cosmetics products up to 0.01% with respect to systemic toxicity. However, its sensitising potential was noted with concern. Isothiazolinones and 2-methyl-1,2-benzisothiazol-3-one were not specifically identified in the European Commission database for information on cosmetic substances and ingredients database.

The [European Chemicals Agency \(ECHA\)](#)¹⁰⁰ and [European Union Pesticides Database](#)¹⁰¹ do not specifically identify isothiazolinones, benzisothiazolinone or 2-methyl-1,2-benzisothiazol-3-one.

New Zealand

The [New Zealand Inventory of Chemicals \(NZIoC\)](#)¹⁰² and the [New Zealand Medicines and Medical Devices Safety Authority \(MedSafe\)](#)¹⁰³ do not specifically identify isothiazolinones, benzisothiazolinone or 2-methyl-1,2-benzisothiazol-3-one.

Canada

The Canadian [Pest Management Regulation Agency](#)¹⁰⁴ and the [Health Canada Drug Product Database](#)¹⁰⁵ do not specifically identify isothiazolinones, benzisothiazolinone or 2-methyl-1,2-benzisothiazol-3-one.

How to respond

Submissions must:

- be relevant to the proposed amendment;
- address matters mentioned in section 52E of the *Therapeutic Goods Act 1989*;
- submitted by the closing date of **18 May 2020** to medicines.scheduling@health.gov.au for substances referred to the ACMS or Joint ACMS-ACCS (Please include 'Proposed Amendments to the Poisons Standard (Medicines/Chemicals)' in the subject line of the email);
- include whether or not you support the amendment/s; and
- be accompanied by a completed [TGA Consultation submission coversheet](#).

⁹⁸ FDA Approved Drug Products Database <https://www.accessdata.fda.gov/scripts/cder/daf/>

⁹⁹ [European Commission database for information on cosmetic substances and ingredients database](#) <https://ec.europa.eu/growth/tools-databases/cosing/>

¹⁰⁰ European Chemicals Agency (ECHA) <https://echa.europa.eu/search-for-chemicals>

¹⁰¹ European Union Pesticides Database <https://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/public/?event=activesubstance.selection&language=EN>

¹⁰² New Zealand Inventory of Chemicals (NZIoC) <https://www.epa.govt.nz/database-search/new-zealand-inventory-of-chemicals-nzioc/DatabaseSearchForm/?SiteDatabaseSearchFilters=36&Keyword=acequinocyl&DatabaseType=NZIOC>

¹⁰³ New Zealand Medicines and Medical Devices Safety Authority (MedSafe)

<https://www.medsafe.govt.nz/profs/class/classintro.asp>

¹⁰⁴ Canada's Pest Management Regulation Agency <https://pesticide-registry.canada.ca/en/active-ingredient-search.html>

¹⁰⁵ Canadian (Health Canada) Drug Product Database <https://health-products.canada.ca/dpd-bdpp/index-eng.jsp>

Submissions might also include:

- Suggested improvements; and/or
- An assessment of how the proposed change will impact on you. That is, what do you see as the likely benefits or costs to you (these may be financial or non-financial). If possible, please attempt to quantify these costs and benefits.

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 **9 September 2020**.

Privacy and your personal information

- The TGA collects your personal information in this submission in order to:
 - Contact you if the TGA wants to seek clarification of issues raised in your submission or to check whether you consent to certain information that you have provided being made publicly available.
 - Help provide context about your submission (e.g. to determine whether you are an individual or a director of a company or representing an interest group).
- The TGA will disclose your name and (if applicable) your designation/work title on the TGA Internet site (i.e. make this information publicly available) if you consent to the publication of your name on the TGA Internet site (please complete the coversheet, see [How to respond](#) above).
- Any text within the body of your submission that you want to remain confidential should be clearly marked 'IN CONFIDENCE' and highlighted in grey.
- Please note that the TGA will not publish personal information about you/others without your/their consent unless authorised or required by law.
- Please do not include personal information about other individuals in the body of your submission. Personal information in this context means information or an opinion about an individual whose identity is apparent, or can reasonably be ascertained, from the information or opinion.

Enquiries

Any questions relating to submissions should be directed by email to medicines.scheduling@health.gov.au (for substances referred to the ACMS or Joint ACCS-ACMS) or chemicals.scheduling@health.gov.au (for substances referred to the ACCS).