Australian Government

Department of Health
Therapeutic Goods Administration

Publication of revised final decisions amending, or not amending, the current Poisons Standard to correct for minor administrative errors, September 2018

28 September 2018

NOTE: the revisions to the final decisions have only been to two decisions being the Cannabidiol, Cannabis and Tetrahydrocannabinols decision and the Appendix J entry for 4-AMINOPROPIOPHENONE decision.

Proposed amendments to the Poisons Standard referred to expert advisory committee

Subdivision 3D.2 of the *Therapeutic Goods Regulations 1990* (the Regulations) sets out the procedure to be followed in circumstances including where the Secretary receives an application under section 52EAA of the *Therapeutic Goods Act 1989* (the Act) to amend the current Poisons Standard and decides to refer the proposed amendment to an expert advisory committee.

Under regulation 42ZCZK, these procedures require (among other things) the Secretary to publish (in a manner the Secretary considers appropriate) a notice specifying the expert advisory committee to which the proposed amendment will be referred, the date of the meeting of the committee and details of the proposed amendment.

Pursuant to regulation 42ZCZK, the Secretary must 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. Such a notice relating to the final decisions referred to herein was made available on the TGA website on 21 December 2017 and the opportunity to make submissions closed on 2 February 2018. Public submissions received on or before this closing date were published on the TGA website at Consultation: Proposed Amendments to the Poisons Standard - ACCS, ACMS and Joint ACCS-ACMS meetings, March 2018 in accordance with subregulation 42ZCZL(3).

Under regulation 42ZCZN of the Regulations, the Secretary, after considering the advice or recommendation of the expert advisory committee, must (subject to regulation 42ZCZO) make an interim decision in relation to the proposed amendment.

Under regulation 42ZCZP of the Regulations, the Secretary must, among other things, publish as soon as practicable (in a manner the Secretary considers appropriate) a notice setting out the interim decision and the reasons for making the interim decision and the proposed date of effect of the proposed amendment (if any).

Also in accordance with regulation 42ZCZP of the Regulations, the Secretary must invite interested persons to make further submissions to the Secretary in relation to the interim decisions by a date mentioned in the notice as the closing date, allowing at least 10 business days after publication of the notice. Such a notice relating to the interim decisions of substances initially referred to the March 2018 meetings of the Advisory Committee on Medicines Scheduling (ACMS #23), the Advisory Committee on Chemicals Scheduling (ACCS #22), and the

Joint Advisory Committee on Medicines and Chemicals Scheduling (ACMS #18) was made available on the TGA website on 7 June 2018 and closed on 5 July 2018 (Publication of interim decisions amending, or not amending, the current Poisons Standard, June 2018). Public submissions received on or before this closing date will be published on the TGA website (Public submissions on scheduling matters) in accordance with regulation 42ZCZQ.

Under regulation 42ZCZR of the Regulations, the Secretary may make a final decision by confirming, varying or setting aside the interim decision, but only after considering all relevant submissions and any advice received in response to a request under paragraph 42ZCZQ(2)(a).

In deciding whether to amend the current Poisons Standard, the Secretary must take into account the matters mentioned in subsection 52E(1) of the Act. These matters include for example, the risks and benefits of the use of a substance, and the potential for abuse of a substance. The Secretary must also comply with (among others) any guidelines of the Australian Health Ministers' Advisory Council referred to the Secretary for the purposes of section 52E of the Act including those set out in the *Scheduling Policy Framework for Medicines and Chemicals*.

Proposed amendments to the Poisons Standard not referred to expert advisory committee

Subdivision 3D.3 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 and decides not to refer the proposed amendment to an expert advisory committee.

Publication of decisions pursuant to regulations 42ZCZS and 42ZCZX of the Therapeutic Goods Regulations 1990

In accordance with regulations 42ZCZS and 42ZCZX, this notice gives effect to the Secretary's obligation to publish the final decisions, the reasons for those decisions and the date of effect of decisions made pursuant to regulations 42ZCZR, 42ZCZO, 42ZCZU or 42ZCZW of the *Therapeutic Goods Regulations 1990*.

The final decisions to which this notice relates include decisions made with respect to:

- scheduling proposals initially referred to the March 2018 meeting of the Advisory Committee on Medicines Scheduling (ACMS #23);
- scheduling proposals initially referred to the March 2018 meeting of the Joint meeting of the Advisory Committees on Chemicals and Medicines Scheduling (Joint ACCS-ACMS #18);
- scheduling proposals initially referred to the March 2018 meeting of the Advisory Committee on Chemicals Scheduling (ACCS #22);
- scheduling proposals on agricultural and veterinary chemicals, as well as new therapeutic Prescription Only medicines known as New Chemical Entities (NCEs) which were not referred to an expert advisory committee; and
- AHMAC approved changes to Appendix J.

Privacy and your personal information

The Therapeutic Goods Administration (TGA) will not publish information it considers confidential, including yours/other individuals' personal information (unless you/they have consented to publication) or commercially sensitive information. Also, the TGA will not publish information that could be considered to be advertising or marketing (e.g. logos or slogans

associated with products), or information about any alleged unlawful activity or that may be defamatory or offensive.

The TGA is part of the Department of Health. For general privacy information, a link to the Department's privacy policy and for contact information if you have a query or concerns about a privacy matter go to Privacy.

The TGA may receive submissions from the public on a proposed amendment to the Poisons Standard where there has been an invitation to the public for submissions on the proposal in accordance with the *Therapeutic Goods Regulations 1990*. These submissions may contain personal information of the individual making the submissions and others.

The TGA collects this information as part of its regulatory functions and may use the information to contact the individual who made the submissions if the TGA has any queries.

As set out above, the TGA is required to publish these submissions unless they contain confidential information.

If you request for your submission to be published in full, including your name and any other information about you, then the TGA will publish your personal information on its website. However, if at any point in time, you change your mind and wish for your personal information to be redacted then please contact the Scheduling Secretariat at MedicinesScheduling@health.gov.au so that the public submissions can be updated accordingly.

Please note that the TGA cannot guarantee that updating the submissions on the TGA website will result in the removal of your personal information from the internet.

Please note that the TGA will not publish personal information about you/others without your/their consent unless authorised or required by law.

Contents

Part A: Amendments to the Poisons Standard referred to an expert advisory committee

1. Advisory Committee on Medicines Scheduling (ACMS #23)

1.1. Diclofenac

Delegate's final decision

The delegate's final decision under regulation 42ZCZR of the *Therapeutic Goods Regulations 1990* (the Regulations) is to amend the Schedule 2 entry for diclofenac in the Poisons Standard to read as follows:

Schedule 2 – Amend Entry

DICLOFENAC when:

a) in divided preparations for oral use containing 12.5 mg or less of diclofenac per dosage unit in a pack containing 20 or less dosage units and labelled with a recommended daily dose of 75 mg or less of diclofenac; or

b) in preparations for dermal use containing 4 per cent or less of diclofenac except in preparations for dermal use containing 2 per cent or less of diclofenac or for the treatment of solar keratosis; or

c) in transdermal preparations for topical use containing 140 mg or less of diclofenac.

Implementation date: ***1 October 2018***

Reasons:

As no new evidence has been received to alter the interim decision for diclofenac, the delegate has confirmed that the final decision and reasons for the final decision are identical to the interim decision.

Public submissions on the interim decision

No public submissions were received before the second closing date in response to an invitation published on 7 June 2018 under regulation 42ZCKP of the Regulations.

Interim decision

The interim decision for diclofenac was published on the TGA website on 7 June 2018 at Publication of interim decisions amending, or not amending, the current Poisons Standard, June 2018 – 1.1 Diclofenac.

Scheduling proposal

The pre-meeting scheduling proposal for diclofenac was published on the TGA website on 21 December 2017 at Consultation: Proposed Amendments to the Poisons Standard - ACCS, ACMS and Joint ACCS-ACMS meetings, March 2018.

1.2. Cannabidiol, cannabis and tetrahydrocannabinols

Delegate's final decision

The delegate's final decision under regulation 42ZCZR of the *Therapeutic Goods Regulations 1990* (the Regulations) is to amend the Schedule 4 entry for cannabidiol, and the Schedule 8 and Appendix K entries for tetrahydrocannabinols and cannabis in the Poisons Standard to read as follows:

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

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

Schedule 8 – Amend Entry

TETRAHYDROCANNABINOLS when extracted from cannabis for human therapeutic use, when:

a) included in products manufactured in accordance with the *Narcotic Drugs Act 1967*; and/or

b) imported as therapeutic goods, or for use in therapeutic goods, for supply, in accordance with the *Therapeutic Goods Act 1989*; and/or

c) 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) in hemp seed oil, containing 50 mg/kg or less of tetrahydrocannabinols when labelled with either of the following warning statements:~~

~~(A) Not for internal use; or~~

~~(B) Not to be taken; or~~

~~iii)~~ii) separately specified in the NABIXIMOLS entry in this Schedule; or

~~iv)~~iii) captured by the CANNABIDIOL entry in Schedule 4.

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 manufactured[1], 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

~~i)~~ii) separately specified in the NABIXIMOLS entry in this Schedule; or

~~ii)~~iii) captured by the CANNABIDIOL entry in Schedule 4; or

~~iii) in hemp seed oil for purposes other than internal human therapeutic use containing 50 mg/kg or less of cannabinoids.~~

Appendix K – Amend Entries

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

TETRAHYDROCANNABINOLS **except** cannabidiol when included in Schedule 4.

Implementation date: ***1 October 2018***

Reasons:

The delegate has confirmed that the reasons for the final decision are identical to the interim decision. Additional reasons for the final decision are the following:

1. References to cannabidiol as an alkaloid ~~has~~ have been deleted as this is incorrect.
2. Wording in the Schedule 4 entry for cannabidiol have been amended for clarity.
3. ~~The w~~Wording in the Schedule 8 entries for ~~entries for~~ tetrahydrocannabinols and cannabis making reference to the Schedule 4 cannabidiol entry ~~has~~ have been amended for clarity.

~~3.~~4. References to hemp seed oil have been deleted in the Schedule 8 entries for tetrahydrocannabinols and for cannabis because hemp seed oil is adequately controlled by the Schedule 9 entry for tetrahydrocannabinols and for cannabis.

Public submissions on the interim decision

No public submissions were received before the second closing date in response to an invitation published on 7 June 2018 under regulation 42ZCKP of the Regulations.

[1] 'Cultivation', 'production' and 'manufacture' have the same meaning as in the *Narcotic Drugs Act 1967*

Interim decision

The interim decision for cannabidiol, cannabis and tetrahydrocannabinols was published on the TGA website on 7 June 2018 at Publication of interim decisions amending, or not amending, the current Poisons Standard, June 2018 – 1.2 Cannabidiol, cannabis and tetrahydrocannabinols.

Scheduling proposal

The pre-meeting scheduling proposal for cannabidiol, cannabis and tetrahydrocannabinols was published on the TGA website on 21 December 2017 at Consultation: Proposed Amendments to the Poisons Standard - ACCS, ACMS and Joint ACCS-ACMS meetings, March 2018.

1.3. Fluticasone

Delegate's final decision

The delegate's final decision under regulation 42ZCZR of the *Therapeutic Goods Regulations 1990* (the Regulations) is to amend the Schedule 2 entry for fluticasone and the index to reflect this change in the Poisons Standard as follows:

Schedule 2 - Amend Entry

FLUTICASONE PROPIONATE (excluding derivatives) in aqueous nasal sprays delivering 50 micrograms or less of fluticasone propionate per actuation when the maximum recommended daily dose is no greater than 400 micrograms, for the prophylaxis or treatment of allergic rhinitis for up to 6 months in adults and children 12 years of age and over.

Index - Amend Entries

FLUTICASONE
cross reference: FLUTICASONE PROPIONATE, FLUTICASONE FUROATE

Schedule 4

FLUTICASONE FUROATE
cross reference FLUTICASONE

FLUTICASONE PROPIONATE

Schedule 4
Schedule 2

Implementation date: ***1 October 2018***

Reasons:

The delegate has confirmed that the reasons for the final decision are identical to the interim decision. Additional reasons for the final decision are the following:

- The Schedule 2 entry should be specific to fluticasone propionate and exclude derivatives, including the more potent analogue, fluticasone furoate.
  - Fluticasone furoate is a more potent analogue of fluticasone propionate available in an aqueous nasal spray for allergic perennial rhinitis, and in formulations used for asthma / COPD[2] containing fluticasone furoate in combination with long acting bronchodilators. Due to the following reasons, fluticasone furoate should remain a Schedule 4 substance, captured under the Schedule 4 entry for 'FLUTICASONE':
    - Fluticasone propionate and fluticasone furoate are distinct drug substances with distinct properties.
    - Fluticasone propionate and fluticasone furoate do not have the same active principle

[2] Chronic obstructive pulmonary disease

and share no common metabolites (neither are metabolised to fluticasone).

§ Fluticasone furoate is more potent with almost twice the receptor binding compared to fluticasone propionate and thus is generally given at lower doses:[3,4]

· There are 6 products containing fluticasone furoate on the Australian Register of Therapeutic Goods (ATRG), all of which are Prescription-Only Medicines (Schedule 4).

Public submissions on the interim decision

No public submissions were received before the second closing date in response to an invitation published on 7 June 2018 under regulation 42ZCKP of the Regulations.

Interim decision

The interim decision for fluticasone was published on the TGA website on 7 June 2018 at Publication of interim decisions amending, or not amending, the current Poisons Standard, June 2018 – 1.3 Fluticasone.

Scheduling proposal

The pre-meeting scheduling proposal for fluticasone was published on the TGA website on 21 December 2017 at Consultation: Proposed Amendments to the Poisons Standard - ACCS, ACMS and Joint ACCS-ACMS meetings, March 2018.

[3] Derendorf, H and Meltzer, EO (2008), 'Molecular and clinical pharmacology of intranasal corticosteroids: clinical and therapeutic implications', *Allergy*, 63, 1292-1300.

[4] Schafer, T *et al* (2011) 'Therapeutic Index (TIX) for intranasal corticosteroids in the treatment of allergic rhinitis', *Rhinology* 49: 272-280

2. Joint meeting of the Advisory Committee on Chemicals and Medicines Scheduling (ACCS/ACMS #18)

2.1. Prostaglandins

Delegate's final decision

The delegate's final decision under regulation 42ZCZR of the *Therapeutic Goods Regulations 1990* (the Regulations) is that the current scheduling of all prostaglandins in the Poisons Standard remains appropriate.

Reasons:

As no new evidence has been received to alter the interim decision for prostaglandins, the delegate has confirmed that the final decision and reasons for the final decision are identical to the interim decision.

Public submissions on the interim decision

No public submissions were received before the second closing date in response to an invitation published on 7 June 2018 under regulation 42ZCKP of the Regulations.

Interim decision

The interim decision for prostaglandins was published on the TGA website on 7 June 2018 at Publication of interim decisions amending, or not amending, the current Poisons Standard, June 2018 – 2.1 Prostaglandins.

Scheduling proposal

The pre-meeting scheduling proposal for prostaglandins was published on the TGA website on 21 December 2017 at Consultation: Proposed Amendments to the Poisons Standard - ACCS, ACMS and Joint ACCS-ACMS meetings, March 2018.

2.2. Vinyl acetate

Delegate's final decision

The delegate's final decision under regulation 42ZCZR of the *Therapeutic Goods Regulations 1990* (the Regulations) is to amend the Schedule 6 entry for vinyl acetate in the Poisons Standard as follows:

Schedule 6 – Amend Entry

VINYL ACETATE MONOMER (excluding its derivatives) **except**:

a) in preparations for therapeutic use; or

b) in cosmetic preparations containing 0.01 per cent or less of vinyl acetate as residual monomer in a polymer; or

c) in other preparations containing 1 per cent or less of vinyl acetate.

Implementation date: ***1 October 2018***

The delegate has decided that the implementation date of 1 October 2018, to replace the 31 October 2017 decision, is reasonable and appropriate in the circumstances.

Reasons:

As no new evidence has been received to alter the interim decision for vinyl acetate, the delegate has confirmed that the final decision and reasons for the final decision are identical to the interim decision.

Public submissions on the interim decision

One (1) public submission was received before the second closing date in response to an invitation published on 7 June 2018 under regulation 42ZCKP of the Regulations. The public submission supported the interim decision for vinyl acetate.

The main point provided in support of the amendment was:

- A thorough analysis was taken and a pragmatic outcome was achieved to ensure a balanced regulatory framework is maintained on vinyl acetate.

The public submission will be made available on the TGA website at Public submissions on scheduling matters.

Interim decision

The interim decision for vinyl acetate was published on the TGA website on 7 June 2018 at Publication of interim decisions amending, or not amending, the current Poisons Standard, June 2018 – 2.2 Vinyl acetate.

Scheduling proposal

The pre-meeting scheduling proposal for vinyl acetate was published on the TGA website on 21 December 2017 at Consultation: Proposed Amendments to the Poisons Standard - ACCS, ACMS and Joint ACCS-ACMS meetings, March 2018.

3. Advisory Committee on Chemicals Scheduling (ACCS #22)

3.1. Mefentrifluconazole

Delegate's final decision

The delegate's final decision under regulation 42ZCZR of the *Therapeutic Goods Regulations 1990* (the Regulations) is to create a new Schedule 5 entry for mefentrifluconazole in the Poisons Standard as follows:

> **Schedule 5 – New Entry**
>
> MEFENTRIFLUCONAZOLE **except** in preparations containing 7.5 per cent or less of mefentrifluconazole.

Implementation date: ***1 October 2018.***

Reasons:

As no new evidence has been received to alter the interim decision for mefentrifluconazole, the delegate has confirmed that the final decision and reasons for the final decision are identical to the interim decision.

Public submissions on the interim decision

No public submissions were received before the second closing date in response to an invitation published on 7 June 2018 under regulation 42ZCKP of the Regulations.

Interim decision

The interim decision for mefentrifluconazole was published on the TGA website on 7 June 2018 at Publication of interim decisions amending, or not amending, the current Poisons Standard, June 2018 – 3.1 Mefentrifluconazole.

Scheduling proposal

The pre-meeting scheduling proposal for mefentrifluconazole was published on the TGA website on 21 December 2017 at Consultation: Proposed Amendments to the Poisons Standard - ACCS, ACMS and Joint ACCS-ACMS meetings, March 2018.

3.2. Moxidectin

Delegate's final decision

The delegate's final decision under regulation 42ZCZR of the *Therapeutic Goods Regulations 1990* (the Regulations) is to amend the Schedules 6 and 4 entries for moxidectin in the Poisons Standard as follows:

Schedule 6 – Amend Entry

MOXIDECTIN:

a) in preparations for external use containing 2.5 per cent or less of moxidectin when packed in single dose tubes for the treatment of cats and dogs; or

b) in preparations for external use containing 2 per cent or less of moxidectin for the treatment of animals; or

c) in preparations for internal use containing 10 per cent or less of moxidectin for the treatment of sheep or cattle,

except when included in Schedule 5.

Schedule 4 – Amend Entry

MOXIDECTIN in preparations for injection containing 10 per cent or less of moxidectin **except** when included in Schedule 5 or 6.

Implementation date: ***1 October 2018***

Reasons:

As no new evidence has been received to alter the interim decision for moxidectin, the delegate has confirmed that the final decision and reasons for the final decision are identical to the interim decision.

Public submissions on the interim decision

No public submissions were received before the second closing date in response to an invitation published on 7 June 2018 under regulation 42ZCKP of the Regulations.

Interim decision

The interim decision for moxidectin was published on the TGA website on 7 June 2018 at Publication of interim decisions amending, or not amending, the current Poisons Standard, June 2018 – 3.2 Moxidectin.

Scheduling proposal

The pre-meeting scheduling proposal for moxidectin was published on the TGA website on 21 December 2017 at Consultation: Proposed Amendments to the Poisons Standard - ACCS, ACMS and Joint ACCS-ACMS meetings, March 2018.

3.3. Eprinomectin

Delegate's final decision

The delegate's final decision under regulation 42ZCZR of the *Therapeutic Goods Regulations 1990* (the Regulations) is to amend the Poisons Standard by creating a new Schedule 6 entry for eprinomectin and amending the Schedule 7 entry to reflect this change as follows:

Schedule 6 – New Entry

EPRINOMECTIN for internal use in preparations containing 5 per cent or less of eprinomectin **except** when included in Schedule 5.

Schedule 7 – Amend Entry

EPRINOMECTIN **except** when included in Schedule 5 or 6.

The Schedule 5 entry remains as follows:

Schedule 5 – Current Entry

EPRINOMECTIN in preparations containing 0.5 per cent or less of eprinomectin.

Implementation date: ***1 October 2018***

Reasons:

The delegate notes the public submission on the interim decision but has decided not to alter the interim decision for eprinomectin because the acute toxicity data for eprinomectin (specifically the oral and dermal toxicity and eye irritation) are consistent with the Schedule 6 criteria of the Scheduling Policy Framework.

The delegate has confirmed that the final decision and reasons for the final decision are identical to the interim decision.

Public submissions on the interim decision

One (1) public submission was received before the second closing date in response to an invitation published on 7 June 2018 under regulation 42ZCKP of the Regulations. The public submission opposed the interim decision, instead supporting of inclusion of the injectable eprinomectin product in Schedule 5. The submission suggested the following alternative wording for the Schedule 5 entry:

EPRINOMECTIN

a) in preparations containing 0.5 per cent or less of eprinomectin;

b) in preparations for internal use containing 5 per cent or less of eprinomectin.

Interim decision

The interim decision for eprinomectin was published on the TGA website on 7 June 2018 at Publication of interim decisions amending, or not amending, the current Poisons Standard, June 2018 – 3.3 Eprinomectin.

Scheduling proposal

The pre-meeting scheduling proposal for eprinomectin was published on the TGA website on 21 December 2017 at Consultation: Proposed Amendments to the Poisons Standard - ACCS, ACMS and Joint ACCS-ACMS meetings, March 2018.

Part B: Amendments to the Poisons Standard not referred to an expert advisory committee

4. Delegate-only decisions on agricultural and veterinary chemicals

4.1. Sodium oxybate

Delegate's final decision

The delegate's final decision under regulation 42ZCZU of the *Therapeutic Goods Regulations 1990* (the Regulations) is to amend the Poisons Standard by creating a new Appendix K entry for sodium oxybate as follows:

Appendix K – New Entry

SODIUM OXYBATE

Implementation date: ***1 October 2018***

Reasons:

The matters under subsection 52E (1) of the *Therapeutic Goods Act 1989* considered by the delegate for the decision include:

(a) the risks and benefits of the use of a substance:

– A common side effect of sodium oxybate is somnolence.

Scheduling proposal and reasons for proposal

The delegate of the Secretary proposed to amend the Poisons Standard with respect to sodium oxybate. The proposed amendment was as follows:

Appendix K – New Entry

SODIUM OXYBATE

My reasons for the proposal were:

· A common side effect of sodium oxybate in somnolence. However, it is not listed in Appendix K of the Poisons Standard.

Background information for sodium oxybate

Current scheduling status

Prior to this final decision sodium oxybate was listed in Schedule 8 and Appendix D of the Poisons Standard as follows:

Schedule 8

SODIUM OXYBATE for human therapeutic use.

Appendix D, Item 1

SODIUM OXYBATE for human use.

Sodium oxybate is also a derivative of 4-hydroxybutanoic acid and its salts listed in Schedule 9 of the Poisons Standard as follows:

Schedule 9

4-HYDROXYBUTANOIC ACID and its salts **except** for sodium oxybate when in Schedule 8. *(GAMMA HYDROXYBUTYRATE (GHB)).

Index

GAMMA HYDROXYBUTYRATE
cross reference: 4-HYDROXYBUTANOIC ACID, GHB, SODIUM OXYBATE

Scheduling history

In November 1991, an applicant wrote to the Drugs and Poisons Scheduling Sub-Committee (DPSSC) requesting that consideration be given to the scheduling of sodium oxybate (gamma hydroxybutyrate) after reports from the United States of America (USA) indicated potential for misuse and serious side effects. The committee felt that more information was required and sought further information from the Drugs of Dependence (DOD) branch, the TGA and State/Territory DPSSC members.

At the May 1992 meeting, the committee noted that gamma-hydroxybutyrate (sodium oxybate) was being used in conjunction with illicit amphetamines and being used as a substitute for anabolic steroids by the fitness/bodybuilding industry. It was also reported that GHB was being sold as 'Fantasy' in night clubs at $80 for 5 grams. As the substance had no approved therapeutic use or safety assessment, the committee felt that scheduling was not appropriate and suggested the DOD branch make the substance a prohibited import.

In November 1994, GHB was on the agenda again and the committee recommended the matter be referred to the Ministerial Committee on Drug Strategy after it was noted that it was a substance of concern to the Australian Bureau of Criminal Intelligence due to substance related deaths in the USA.

In November 1996, the committee approved an out of session Schedule 9 proposal for sodium oxybate. The committee agreed to create a new Schedule 9 entry for 4-hydroxybutanoic acid. However, due to concerns that the entry may inadvertently capture derivatives that were not of concern, the committee agreed to amend the entry to read 4-hydroxybutanoic acid and its salts so that salts could be clearly captured by the entry. Sodium oxybate was also added to the index entry for 4-hydroxybutanoic acid as a cross reference.

In June 2002, the NDPSC considered gamma-butyrolactone (GBL) as a possible derivate of GHB and as a result, the 4-hydroxybutanoic acid entry was reviewed. The committee agreed that the current scheduling of 4-hydroxybutanoic acid is consistent with the committee's intent to

exclude other derivatives of 4-hydroxybutanoic acid, except its salts, from the requirements of scheduling. This was due to them being appropriately controlled through other State and Territory mechanisms. Therefore, GBL remained unscheduled.

In March 2014, the Advisory Committee on Medicines Scheduling (ACMS) considered a proposal to create new entries for sodium oxybate in Schedule 8 and Appendix D, Item 1. The committee recommended that the new entries be created for sodium oxybate due to it being safe and efficacious at the therapeutic dose of 9 grams, the therapeutic need and the low potential for abuse. The committee also recommended that the Schedule 9 GHB entry be amended to exclude the Schedule 8 entry for sodium oxybate. The delegate agreed with the committee and the new entries were implemented 1 October 2014.

Australian regulations

The Australian Register of Therapeutic Goods (ARTG) has no products containing sodium oxybate.

Sodium oxybate does not appear in the current Therapeutic Goods (Permissible Ingredients) Determination No.5 of 2017 as it is a scheduled substance and is not eligible for use in ARTG listed medicines.

In the last 30 years there have been no reported cases of adverse events related to sodium oxybate in the Database of Adverse Events Notification (DAEN) - Medicines.

International regulations

- **USA**: sodium oxybate is classified as a prescription medicine.
- **European Union (EU)**: The European Commission granted a marketing authorisation valid throughout the EU for Xyrem® on 13 October 2005.
- **Canada**: Health Canada regulates sodium oxybate as a 'Narcotic (CDSA I)' medicine.
- **United Kingdom (UK)**: sodium oxybate is classified as a prescription medicine.

Substance summary

Sodium oxybate is the sodium salt of gamma hydroxybutyrate (GHB) and is a central nervous system depressant which is used to treat excessive daytime sleepiness and cataplexy in patients with narcolepsy and modifies sleep architecture reducing fragmented night-time sleep. The chemical name for sodium oxybate is sodium 4-hydroxybutyrate. The precise mechanism by which sodium oxybate produces an effect is unknown. However, sodium oxybate is thought to act by promoting slow (delta) wave sleep and consolidating night-time sleep.

Delegate's considerations

The delegate considered the following in regards to this proposal:

- The Australian Health Ministers' Advisory Council's Scheduling Policy Framework (SPF 2018); and
- Section 52E (1) of the *Therapeutic Goods Act 1989* in particular: (a) the risks and benefits of the use of a substance.

4.2. *Cyprinid herpesvirus-3*

Delegate's final decision

The delegate's final decision under regulation 42ZCZU of the *Therapeutic Goods Regulations 1990* (the Regulations) is to amend the Poisons Standard by creating a new Appendix B entry for *Cyprinid herpesvirus-3* as follows:

Appendix B – New Entry

CYPRINID HERPESVIRUS-3

Reasons for entry: a (low toxicity)

Areas of use: 1.10 (biological control agent)

Implementation date: ***1 October 2018***

Reasons:

The matters under subsection 52E (1) of the *Therapeutic Goods Act 1989* considered by the delegate for the decision include:

(a) the risks and benefits of the use of a substance:

- *Cyprinid herpesvirus-3* (CyHV-3) is a naturally occurring viral organism present in several countries and specifically targets the common carp. CyHV-3 is not infective or pathogenic in other fish or mammals, including humans.
- There is no evidence of a fish virus causing any adverse effects in humans.
- CyHV-3 genome appears stable relative to that of other known viruses.
- CyHV-3 DNA sequence shares very little similarity with the sequence of mammalian herpes viruses.
- CyHV-3 does not replicate above 28°C, hence mammalian body temperatures (mean ~38°C) are not compatible with CyHV-3 infectivity.

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

- CyHV-3 will be used as a specific pesticide for the common carp for the purposes of the National Carp Control Plan.

(c) the toxicity of a substance:

- CyHV-3 is not infective or pathogenic in humans or animals other than the common carp.

Applicant's scheduling proposal and reasons for proposal

An application was submitted by the Australian Pesticides and Veterinary Medicines Authority (APVMA) to consider the scheduling of Cyprinid herpesvirus-3 (CyHV-3) in the Poisons Standard. The application proposed that CyHV-3 does not require scheduling.

The applicant's reasons for the proposal were:

- CyHV-3 is a naturally occurring viral organism present in several countries and specifically targets the common carp. No other fish is affected by CyHV-3 and testing in other animals, including mammals, has demonstrated that CyHV-3 is not infective to them.
- CyHV-3 is not currently present in the Australian environment. Since identification of CyHV-3 two decades ago, human exposure to the virus has been extensive across several countries through oral and dermal routes. Despite extensive human exposure to fish viruses in general, and to CyHV-3 in particular, there is no evidence of a fish virus causing any adverse effects in humans.
- CyHV-3 genome appears stable relatively to that of other known viruses. CyHV-3 DNA sequence shares very little similarity with the sequence of mammalian herpes viruses.
- CyHV-3 does not replicate above 28°C, hence mammalian (mean ~38°C) and bird body temperatures (mean ~40°C) are not compatible with CyHV-3 infectivity.

Background information for *Cyprinid herpesvirus-3*

Current scheduling status and scheduling history

Prior to this final decision CyHV-3 was not scheduled in the Poisons Standard. CyHV-3 has not been previously considered for scheduling.

Australian regulations

The Australian Government is embarking on a revolutionary, long-term plan to rid our waterways of the common carp, one of the country's most devastating pests. On 1 May 2016, the government announced that it is investing $15 million over two and half years to undertake further research, approval and consultation to develop a comprehensive National Carp Control Plan for a potential release of Cyprinid herpesvirus (carp herpesvirus) by the end of 2018. See the National Carp Control Plan on the Australian Government Department of Agriculture and Water Resources website for more information.

CyHV-3 is not currently approved by the APVMA.

CyHV-3 is not used in human therapeutics and therefore does not appear to be in any products on the Australian Register of Therapeutic Goods (ARTG) nor in the Therapeutic Goods (Permissible Ingredients) Determination.

International regulations

There do not appear to be international regulations for CyHV-3.

Substance summary

The *Cyprinid herpesvirus-3* (or CyHV-3) is a naturally occurring viral organism in several countries. CyHV-3 is the causative agent of a highly contagious, fatal disease which specifically targets common carp.

Infectivity and pathogenicity

CyHV-3 is not infective or pathogenic in humans. The human health hazard of CyHV-3 is considered to be negligible.

Acute toxicity studies with CyHV-3 were not undertaken. Nevertheless, considering CyHV-3 has a negligible human health hazard, it is postulated that CyHV-3 would not reach a classification according to the Scheduling Policy Framework for Medicines and Chemicals (SPF, 2018).

Delegate's considerations

The delegate considered the following in regards to this proposal:

- The applicant's scheduling application to amend the current Poisons Standard with respect to *Cyprinid herpesvirus-3*;
- The Australian Health Ministers' Advisory Council's Scheduling Policy Framework (SPF 2018); and
- Section 52E (1) of the *Therapeutic Goods Act 1989* in particular: (a) the risks and benefits of the use of a substance; (b) the purposes for which a substance is to be used and the extent of use of a substance; and (c) the toxicity of a substance.

4.3 Appendix J

Delegate's final decision

The delegate's final decision under regulation 42ZCZU of the *Therapeutic Goods Regulations 1990* (the Regulations) is to amend Appendix J of the Poisons Standard as follows:

Appendix J - Schedule 7 Poisons requiring additional controls on availability and use

Part 1 - Authorisation considerations for availability and use

All poisons included in this Appendix are not to be available except to authorised or licensed persons.

The use of a poison may be restricted for a particular purpose. Controls recommended for the Schedule 7 poisons listed in the table below may be implemented through poisons controls or other State or Territory legislation.

Authorisation considerations

a	Poisons marked with 'a' are restricted to analytical or research purposes only.
p	Poisons marked with 'p' have been identified as representing a significant risk to public health. Additional restrictions on their possession and use must be applied through an authorisation or licensing process which includes a case by case assessment of risks to public health.

PART 2

A poison listed in this Appendix is to be available in accordance with the authorisations considerations specified beside it in the "Authorisation Considerations" column.

Poisons	Authorisation considerations
ABAMECTIN	
ACIBENZOLAR-S-METHYL	
ACROLEIN	
ACRYLONITRILE	
ALACHLOR	a
ALLYL ALCOHOL	
4-AMINOPROPIOPHENONE	~~a~~p

	4-AMINOPYRIDINE	
	ARPRINOCID	a
	ARSENIC	p
	AZOCYCLOTIN	a
	BENZENE	
	BIFLUORIDE	
	BORON TRIFLUORIDE	
	BRODIFACOUM	
	BROMADIOLONE	
	BROMINE	
	BRUCINE	
	CALCIFEROL	
	CAPTAFOL	a
	CARBADOX	
	CARBON TETRACHLORIDE	
	CARBONYL SULFIDE	
	CHLORDECONE	a
	CHLORDIMEFORM	a
	CHLORINE	
	CHLOROMETHIURON	a
	CHLOROPICRIN	
	4-CHLORO-*o*-TOLUIDINE	a

	COLECALCIFEROL	
	COUMATETRALYL	
	CYANOGEN	
	CYHEXATIN	a
	4,4-DIAMINODIPHENYLMETHANE	
	1,2-DIBROMO-3-CHLOROPROPANE	a
	1,3-DICHLOROPROPENE	
	DIFENACOUM	
	4-DIMETHYLAMINOAZOBENZENE	a
	DINITROCRESOLS	a
	DINITROPHENOLS	a
	DINOSEB	a
	EPICHLOROHYDRIN	
	EPIDERMAL GROWTH FACTOR	
	ETACONAZOLE	a
	ETHYLENE DIBROMIDE	a
	ETHYLENE OXIDE	
	FLUOROACETAMIDE	p
	FLUOROACETIC ACID	p
	FOLPET	
	HALOFUGINONE	
	HALOGENATED DIBENZODIOXINS AND	a

	DIBENZOFURANS	
	HCB	a
	HYDROCYANIC ACID AND CYANIDES	p
	HYDROFLUORIC ACID	
	HYDROSILICOFLUORIC ACID	
	IODOMETHANE	
	MADURAMICIN	
	MERCURY	
	METHACRIFOS	
	METHOXYETHYLMERCURIC ACETATE	a
	METHOXYETHYLMERCURIC CHLORIDE	
	METHYL BROMIDE	
	4,4'-METHYLENEBIS[2-CHLOROANILINE]	
	MIREX	a
	MOLINATE	
	NICOTINE	
	NITROFEN	a
	PHENYLMERCURIC ACETATE	
	PHOSPHIDE, metallic	
	PHOSPHINE	
	PROPYLENE OXIDE	
	PYRINURON	a

STRYCHNINE	p
SULCOFURON	a
TETRACHLOROETHANE	
2,2',6,6'-TETRAISOPROPYL-DIPHENYL-CARBODIIMIDE	
THALLIUM	p
o-TOLIDINE	
VINYL CHLORIDE	

I have also decided that the following three factors are added to Appendix J criteria in the Australian Health Ministers' Advisory Council's Scheduling Policy Framework (SPF 2018):

1. Significant, or potential to cause, severe and possible irreversible injury may occur without the individual being aware of exposure - whether that is a single or repeated exposure or a low or high dose exposure.
2. Specialised skills and/or equipment are required to mitigate the risks of using the poison.
3. The patterns of use of the poison pose an unacceptable risk resulting from direct or indirect exposure to the public.

Implementation date: ***1 October 2018***

Reasons:

- Appendix J poisons be available only to authorised or licensed persons.
- The use of Appendix J poisons that are banned, obsolete or subject to international conventions should be restricted to analytical and research purposes only.
- States and Territories use Appendix J to inform regulatory controls and practices.
- The use patterns for 27 of the 80 Appendix J poisons have changed over time due to factors such as:
  - Being subject to international conventions to which Australia is a party
  - Being banned based on evidence of harm to people and/or the environment
- No longer registered for pesticide and veterinary uses with the Australian Pesticides and Veterinary Medicines Authority (APVMA). These poisons were not identified as having a use beyond analytical or research purposes. The use of a poison in this context does not pose a significant public health risk although some of them are still permitted for use or are being manufactured in other countries. Therefore the possibility of unlawful supply and possession of these poisons and potential public health risk in Australia remains.

- Regulatory agencies will benefit from additional guidance on poisons subject to national or international restrictions to ensure appropriate controls are applied.
- Previous Appendix J included four conditions (1-4), although only two of the conditions were applied (1 and 3).
  - Condition 1 (*Not to be available except to authorised or licensed persons*) applies to 76 of the 80 poisons;
  - Condition 3 (Not to be used except by or in accordance with the directions of accredited government vermin control officers.) applies only to 4 -aminopropiophenone, fluoroacetic acid, fluoroacetamide and thallium.
- Condition 3 is outdated with respect to current vertebrate pest management practices and terminology. The intent of the control to limit the use of the specified Appendix J poisons is supported by State and Territory vertebrate pest management frameworks that identify persons accessing and using these poisons.
- Trichloroisocyanuric Acid – no longer has an S7 listing and thus does not meet the current inclusion requirements for Appendix J

Cyanide, strychnine, thallium, fluoroacetic acid, fluoroacetamide, hydrocyanic acid and arsenic - these poisons were previously listed in Part 3 paragraph 41 of the SUSMP as poisons representing such a risk to public health that persons seeking to possess and use them had to hold specific authorisation from an appropriate authority. An inadvertent omission in 2015 removed the additional control over possession from the current version of the SUSMP. The controls need to be reinstated to ensure the continued management of public health risk.

The matters under subsection 52E (1) of the *Therapeutic Goods Act 1989* considered relevant by the delegate for the decision include:

- The outcomes report of the Appendix J review conducted by the Interjurisdictional Working Group Poisons Control (IJWPC) which includes consultation responses;
- The letter to the Secretary of the Department of Health from the chair of the IJWPC dated 18 April 2018;
- An email from the IJWPC dated 27 July 2018 confirming Appendix J amendments;
- Appendix J consultation paper dated May 2017;
- The Australian Health Ministers' Advisory Council's Scheduling Policy Framework (SPF 2018); and
- Section 52E of the *Therapeutic Goods Act 1989*, in particular (a) the risks and benefits of the use of a substance; (b) the purposes for which a substance is to be used and the extent of use of a substance; (c) the toxicity of a substance; (d) the dosage, formulation, labelling, packaging and presentation of a substance; (e) the potential for abuse of a substance; and (f) any other matters that the Secretary considers necessary to protect public health.

Applicant's scheduling proposal and reasons for proposal

The review of Appendix J completes the actions that were agreed to by the Australian Health Ministers Advisory Council (AHMAC) to achieve national consistency of controls on poisons in response to the 2008 Productivity Commission Research Report on Chemicals and Plastics Regulation.

Background information for Appendix J

Appendix J Review:

- Review of Appendix J is the final deliverable – AHMAC 2013 Implementation Plan for Productivity Commission's Chemical Regulation Reforms.
- DECISION RIS The NCCTG Strategies to implement a national approach to poisonous chemical controls:
  - Undertake assessment of risk posed by the chemicals.
  - Update the poisons currently in Appendix J that are subject to additional controls to reflect contemporary use patterns.
- Qld agreed to lead with support from interjurisdictional working group formed under AHMAC.
- Review commenced in 2015.

Appendix J - current status

- Appendix J currently contains eighty (80) S7 poisons identified as requiring additional controls on their availability and use.
- These poisons have uses in industrial, manufacturing, agricultural, veterinary, research and analytical purposes.
- There are variations in the way jurisdictions have implemented controls over Appendix J poisons.
- Controls are administered by agriculture, health and/or workplace health and safety portfolios.
- Some jurisdictions also have expanded the scope beyond Appendix J.

Review process

- Examine the availability, contemporary use patterns and potential for public exposure of Appendix J poisons.
- Review toxicity – updated profiles, studies etc. if available.
- Examine non-Appendix J S7 poisons currently subject to jurisdictional controls of availability, possession, and use.
- Examine adequacy of existing controls.
- Develop criteria for inclusion of S7 poisons in Appendix J.

Review findings

- Discontinued uses
  - applies to 27 of the 80 Appendix J poisons
  - subject to international conventions, are banned or no longer registered by the APVMA

- Scheduling review
  - Trichloroisocyanuric acid – no longer an S7 poison
  - 4-dimethylaminobenzene – could be included in the current broader review of the scheduling of azo dyes
- Errors
  - An inadvertent omission in 2015 resulted in removal of public health controls over certain poisons listed in Part 3 paragraph 41 of the SUSMP
- Review current controls
  - Appendix J includes four conditions, although only two of the conditions are applied as per table below:

#	**Condition**	**Condition status**
1.	Not to be available except to authorised or licensed persons.	In use
2.	Not to be used in printing inks.	Not in use
3.	Not to be used except by or in accordance with the directions of accredited government vermin control officers.	In use
4.	Not to be used in industries which handle, process or store foods, animal feeds or packaging materials.	Not in use

  - Condition 1 applies to 76 of the 80 poisons
  - Condition 3 applies only to PAPP, fluoroacetic acid, fluoroacetamide and thallium

Changes to Appendix J Endorsed by AHMAC December 2017

- All 78 poisons to be only accessed and used by authorized or licensed persons
- Authorization may be under WHS, agricultural or health legislation
- Two poisons to be referred for scheduling review
- Outdated conditions to be removed
- 27 poisons with discontinued use to be only used for analytical or research purposes
- Controls for possession and use for 7 poisons in the former Part 3, 41(3) of SUSMP to be reinstated
- Name to be changed to "Schedule 7 Poisons Requiring Additional Controls on Availability and Use"
- Endorsed the scheduling factors for inclusion of a Schedule 7 poison in Appendix J

Delegate's considerations

The delegate considered the following in regards to this proposal:

- The applicants scheduling proposal to update Appendix J
- The outcomes report of the Appendix J review conducted by the Interjurisdictional Working Group Poisons Control (IJWPC) which includes consultation responses;
- The letter to the Secretary of the Department of Health from the chair of the IJWPC dated 18 April 2018;
- An email from the IJWPC dated 27 July 2018 confirming Appendix J amendments;
- Appendix J consultation paper dated May 2017;
- The Australian Health Ministers' Advisory Council's Scheduling Policy Framework (SPF 2018); and
- Section 52E of the *Therapeutic Goods Act 1989*, in particular (a) the risks and benefits of the use of a substance; (b) the purposes for which a substance is to be used and the extent of use of a substance; (c) the toxicity of a substance; (d) the dosage, formulation, labelling, packaging and presentation of a substance; (e) the potential for abuse of a substance; and (f) any other matters that the Secretary considers necessary to protect public health.

5. Delegate-only decisions on medicines for human therapeutic use: New Chemical Entities (NCEs)

5.1 Safinamide

Delegate's final decision

The delegate's final decision under regulation 42ZCZU of the *Therapeutic Goods Regulations 1990* (the Regulations) is to amend the Poisons Standard by creating new Schedule 4, Appendix K and Appendix L entries for safinamide as follows:

Schedule 4 – New Entry

SAFINAMIDE.

Appendix K – New Entry

SAFINAMIDE

Appendix L – New Entry

SAFINAMIDE

Warning statement/s: 62 (Do not use if pregnant), 76 (Do not become pregnant during use or within (Insert number of months as per approved Product Information) month(s) of stopping treatment), 77 (WARNING - May cause birth defects).

Implementation date: ***1 October 2018***

Reasons:

The matters under subsection 52E (1) of the *Therapeutic Goods Act 1989* considered by the delegate for the decision include:

(a) the risks and benefits of the use of a substance:

- Safinamide is a highly selective and reversible inhibitor of monoamine oxidase B to be potentially approved for idiopathic Parkinson's disease. In these uses the benefits are considered to outweigh risks at a population level.

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

- Adult patients with idiopathic Parkinson's disease (PD). Accordingly, the extent of use of the product is relatively limited to PD patients only

(c) the toxicity of a substance:

- Safinamide has its own distinct toxicities but these have been addressed within the benefit/risk consideration noted above.

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

- The dose regimen, formulation, labelling, packaging and presentation of Safinamide have been considered and none of these aspects precludes scheduling of Safinamide as Schedule 4.

Scheduling proposal

The delegate of the Secretary proposed to amend the Poisons Standard with respect to safinamide, a new chemical entity (NCE) for human therapeutic use.

Background information for safinamide

Scheduling status

Safinamide is not specifically scheduled and is not captured by any entry in the Poisons Standard.

Delegate's consideration

The delegate considered the following in regards to this scheduling:

- Advice on the place in therapy of this NCE;
- The Australian Health Ministers' Advisory Council's Scheduling Policy Framework (SPF 2018); and
- Section 52E(1) of the *Therapeutic Goods Act 1989* in particular: (a) the risks and benefits of the use of a substance; (b) the purposes for which a substance is to be used and the extent of use of a substance; (c) the toxicity of a substance; and (d) the dosage, formulation, labelling, packaging and presentation of a substance.

5.2 Tilmanocept

Delegate's final decision

The delegate's final decision under regulation 42ZCZU of the *Therapeutic Goods Regulations 1990* (the Regulations) is to amend the Poisons Standard by creating a new Schedule 4 entry for tilmanocept as follows:

Schedule 4 – New Entry

TILMANOCEPT.

Implementation date: ***1 October 2018***

Reasons:

The matters under subsection 52E (1) of the *Therapeutic Goods Act 1989* considered by the delegate for the decision include:

(a) the risks and benefits of the use of a substance:

- Tilmanocept is a new chemical entity with no clinical or marketing experience in Australia.

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

- Tilmanocept is a diagnostic, receptor-targeted, radiopharmaceutical developed for the detection of sentinel lymph nodes. It is indicated for imaging and intraoperative detection of sentinel lymph nodes draining a primary tumour in adult patients with breast cancer, melanoma, or localised squamous cell carcinoma of the oral cavity.

(c) the toxicity of a substance:

- The potential toxicity of tilmanocept includes hypersensitivity reactions, including anaphylaxis.
- Tilmanocept is Pregnancy Category C. There are no data from the use of Tilmanocept in pregnant women.

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

- Tilmanocept will require specialised facilities and trained staff for preparation and administration and should only be administered by trained healthcare professionals with appropriate technical expertise.

Scheduling proposal

The delegate of the Secretary proposed to amend the Poisons Standard with respect to tilmanocept, a new chemical entity (NCE) for a human therapeutic medicine.

Background information for safinamide

Scheduling status

Tilmanocept is not specifically scheduled and is not captured by any entry in the Poisons Standard.

Delegate's consideration

The delegate considered the following in regards to this scheduling:

- Advice on the place in therapy of this NCE;
- The Australian Health Ministers' Advisory Council's Scheduling Policy Framework (SPF 2018); and
- Section 52E(1) of the *Therapeutic Goods Act 1989* in particular: (a) the risks and benefits of the use of a substance; (b) the purposes for which a substance is to be used and the extent of use of a substance; (c) the toxicity of a substance; and (d) the dosage, formulation, labelling, packaging and presentation of a substance.